A HEALTH CARE QUALITY IMPROVEMENT SYSTEM FOR MEDICAID MANAGED CARE

A Guide for States

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION
MEDICAID BUREAU
July 6, 1993

A HEALTH CARE QUALITY IMPROVEMENT SYSTEM

FOR MEDICAID MANAGED CARE

A GUIDE FOR STATES

July 6, 1993

Medicaid Bureau
Health Care Financing Administration
U.S. Department of Health and Human Services

FORWARD

The Medicaid program is facing unprecedented challenges in delivering health care to our nation's most vulnerable citizens. Large and simultaneous growth in eligible and health care needy individuals, covered services, and costs of care have challenged State Medicaid programs as never before to find the most efficient and effective strategies for providing access to high quality health care at controllable cost.

Many States have turned to "coordinated" or "managed" care programs to meet these concurrent objectives. As of June of 1992, thirty-six States used managed care arrangements to serve approximately 3.6 million Medicaid recipients. This represented a 35% growth from 1991 to 1992. During this period, Prepaid Health Plan enrollment increased 69% to 750,000; Primary Care Case Management Program (fee-for-service, non-risk reimbursed forms of managed care) enrollment increased 43% to 1.2 million and HMO enrollment increased 20% to 1.7 million.

The Medicaid Bureau is pleased with these State achievements in increasing use of managed care. States have shown that it is possible to increase access to and utilization of appropriate services while containing costs. But more importantly, States are now demonstrating that quality of care features in managed care have the ability to influence health outcomes; for example, by reducing infant mortality.

Because of this potential, it is critical to make maximal use of managed care's unique capabilities in health care quality improvement. To this end, in 1991 the Medicaid Bureau began the Quality Assurance Reform Initiative (QARI) to develop a Health Care Quality Improvement System for Medicaid managed care programs. This document represents the product of Phase I of this initiative. It contains: a framework for a health care quality improvement system for Medicaid managed care; recommended standards for internal quality assurance programs of managed care organizations; recommendations regarding priority clinical areas of concern, use of clinical indicators and practice guidelines; and a recommended scope of work for conducting external quality reviews. The product of two years of collaborative work by the State Medicaid Directors' Technical Advisory Group on managed care, representatives from the managed care industry, advocates for Medicaid recipients and the Health Care Financing Administration's Medicaid Bureau, the content of this document was designed from the start to be appropriate for all States and all capitated or other risk-reimbursement forms of managed care.

The Medicaid Bureau recognizes however, that all States and managed care organizations do not currently have in place quality improvement programs and systems that meet the recommended standards described in this document. This document was not

intended to document the current status of quality assurance / quality improvement activities in Medicaid managed care programs. Rather, it is intended to chart a course of action for States and plans that serve the Medicaid population, so that they may take steps to increase the effectiveness of their health care quality improvement systems, especially at a time when many of them are undertaking substantial expansions of their Medicaid managed care programs.

Federal and State governments and the managed care industry have important responsibilities and much work to do to in creating and strengthening such systems. This work will not always be easy or quickly accomplished. It can, however, be facilitated by strong partnerships between the public and private sectors dedicated to implementing reliable health care quality improvement systems for Medicaid managed care that are appropriate to the unique needs of each State. Such partnerships will be necessary in order to resolve the many substantial issues facing State Medicaid Agencies as they work to create Health Care Quality Improvement Systems in their States. The reader is directed to the introduction to this manual, "Important Issues Which Should Be Addressed Prior to and Concurrent With the Use of These Guidelines." The content of this section should be carefully considered and reflected in the approaches which States pursue to implement the guidelines contained in this manual.

HCFA's Medicaid Bureau intends to assess, monitor, and make improvements to these guidelines on an ongoing basis. In this activity we will be significantly informed by a demonstration and evaluation of these guidelines in three States under funding from the Henry J. Kaiser Family Foundation. (See Appendix B.) Further, the Medicaid Bureau, working with advocacy organizations, the managed care industry, and experts in quality assessment and improvement technology, is committed to providing States with additional technical assistance to aid them in their own quality assurance reform initiatives.

The dissemination of this document serves as the Medicaid Bureau's first step in advancing the application of quality improvement technology to Medicaid managed care programs. We hope that it will make a significant contribution to the way in which health care is delivered to Medicaid recipients.

ACKNOWLEDGEMENTS

Many individuals and groups have contributed to and supported this Quality Assurance Reform Initiative for Medicaid managed care. The Medicaid Bureau would like to express here our sincere and great appreciation of the time, knowledge and experience given to this initiative in general, and to the production of this document in particular.

Allan J. Chernov, M.D., of Medica; Leonard J. Kirschner, M.D., M.P.H., of the Arizona Health Care Cost Containment System; Maureen Mangotich, M.D., formerly of Health Alliance Plan of Michigan and now of Aetna Health Plan; Donald M. Nielsen, M.D., of Kaiser Permanente; Bruce Perry, M.D., of Group Health Cooperative of Puget Sound; Gerald R. Plotkin, M.D., of Harvard Community Health Plan; N.S. Rangarajan, M.D., of Comprehensive Health Services of Detroit; Michael Stocker, M.D., formerly of US Health Care and now of CIGNA Healthplan Inc.; and Bruce Wilson, M.D., of Rocky Mountain HMO, who together formed an ad-hoc Medical Directors Group advisory to this project, generously gave of their time and expertise in the creation of Chapters 2, 3 and 4 of this manual. We thank both the Group Health Association of America (GHAA) and the American Managed Care and Review Association (AMCRA) for both nominating the Medical Directors to serve on this project and for their subsequent review of and comment on this document.

In addition, Patricia MacTaggert, formerly of the Minnesota Department of Human Services and now with Delta Dental Plan of Minnesota contributed her extensive knowledge and experience as liaison to the Medical Directors Group and member of the State Medicaid Directors' Technical Advisory Group on Medicaid Coordinated Care, which had primary responsibility for the creation of Chapter One of this report.

We thank Patricia A. Riley, Executive Director of the National Academy for State Health Policy for so ably serving as Chair of the Medical Directors Group and also for providing liaison to the National Task Force on Medicaid Managed Care.

State Medicaid agencies and HCFA Regional Offices also performed extensive review of all draft documents. We thank them for their commitment of resources to this

effort and for sharing their valuable experiences in monitoring and reviewing quality of health care.

We are also very grateful to the National Committee for Quality Assurance which generously shared its expertise in health care quality improvement technology and offered consultation, encouragement and support for this project.

In addition, we extend our sincere appreciation to the U.S. Public Health Service's Maternal and Child Health Bureau for the consultation provided by Ann Koontz, C.N.M., Dr.P.H. on appropriate clinical indicators for monitoring health care for pregnant women.

Finally, the analytical work underpinning this document and the writing of the documents which together comprise this manual was provided by Ann Page, R.N., M.P.H. in the Medicaid Managed Care Office. Her efforts were key to the production of this document and for concluding this phase of the QARI.

TABLE OF CONTENTS

continued on next page

TABLE OF CONTENTS (continued)

INTRODUCTION

IMPORTANT ISSUES WHICH SHOULD BE ADDRESSED PRIOR TO AND CONCURRENT WITH THE USE OF THESE GUIDELINES

The information in this manual is designed to give assistance to States in creating effective systems of quality assessment and improvement for Medicaid managed care. While the word "system" is generally overworked, it is important to appreciate the difference between creating a quality improvement program within the confines of a single organizational entity versus creating a coordinated quality assessment and improvement effort that involves a variety of private and governmental organizations. While both efforts have much in common, the creation of an inter-organizational, public-private system can be complicated by intensified problems in: differing understandings by the participating entities of the goals of quality assessment and improvement; variation in level of available resources throughout the system; lack of common understanding of the roles of the various components of the system; and different views of accountability for quality assessment and improvement, to name but a few. This introductory section highlights a few such issues which will be critical to the successful development of a health care quality improvement system in each State. States are encouraged to consider these issues both before embarking upon and during implementation of their Health Care Quality Improvement Systems (HCQIS) for Medicaid Managed Care.

1. **ESTABLISHMENT OF HCQIS STANDARDS APPROPRIATE FOR THE STATE:** Except where, in Chapter 1, specific statutory or regulatory references are given, the guidelines contained in this document are precisely that: guidelines. They were not developed as and should not be treated as minimum performance standards for immediate compliance by all managed care contractors. They are presented herein to States for their review and selection of those which are appropriate for their State. In several instances, in Chapters 3 and 4 for example, States are presented with optional approaches for fulfilling a particular guideline.

In order to be successful, a State's HCQIS standards need to be developed with the participation of all components of the system, including: managed care contractors, other State regulating bodies, Medicaid recipients or their representatives, and external review organizations, if appropriate. The purpose of such input is to identify which of the standards contained in this manual, or others, are appropriate standards for its own Health Care Quality Improvement System. Suggested ways in which States can solicit this participation include: the establishment of ad-hoc work groups, public meetings for receipt of formal comments, dissemination of the States' recommended standards for written comments, or other mechanisms.

2. **AVOIDANCE OF DUPLICATE MONITORING:** Capitated or risk-reimbursed managed care organizations may be subject to a number of regulatory reviews, which may address quality of care, as well as other areas of concern. It can be cost-effective for both the State and the managed care organization if the State's HCQIS for Medicaid managed care builds on, or is coordinated with, these other review processes. For example, the Medicaid agency and the State licensing entity could identify what areas of concern they have in common, how to make their standards in these areas as consistent as possible, and how to coordinate their review activities, ideally so that one review or component of a review could satisfy the standards or a component of the standards of the other. Such coordination should assure that the actual reviews are conducted in a satisfactory manner in addition to assuring that the actual standards being monitored are consistent.

3. **VARIATION IN QUALITY IMPROVEMENT SYSTEMS AND NEED FOR PHASE-IN PERIOD:** States and their managed care contractors will likely vary in the speed and methods by which they can implement the guidelines contained in this document. We know, for example, that States with longer experience in managed care contracting often have more developed quality assessment and improvement mechanisms and resources. Similarly, a managed care plan's internal quality assurance program can also be a reflection of its size, age and financial position, in addition to its commitment to quality improvement. Because of the potential for variation in capability, a State's plan for implementing its HCQIS should determine the appropriate phase-in period to allow plans which are not as far along in the development of their own internal programs to take reasonable actions necessary to achieve compliance with the standards adopted by the State.

4. **CALCULATION OF COSTS FOR IMPLEMENTING THE HCQIS:** This document does not address any potential new costs which both States and managed care contractors may incur if a State decides to implement a HCQIS which places additional responsibilities on itself and its contractors. Depending upon: past practices of both the State and its contractors; the degree of their commitment to quality assessment and improvement; and the HCQIS standards which the State adopts, there may be additional cost considerations. In planning for the implementation of a new or modified HCQIS, the State should undertake activities to assess what the basic quality assurance expectations are for an HMO in the State; e.g., the expectations of employers/private purchasers in the State; State licensing requirements; the extent of NCQA accreditation of managed care plans in the State and any other standards for quality assurance utilized in the State. This information has implications both for the selection of HCQIS standards appropriate for the State and for the issue of additional costs for implementation of a HCQIS.

5. IDENTIFICATION OF TECHNICAL ASSISTANCE / EDUCATION NEEDS FOR THE HCQIS: Both the State and other components of the HCQIS may need to develop new areas of expertise in order to implement a HCQIS in accordance with the goals and standards the State Medicaid Agency adopts. As a result, States should determine, as part of the process used to determine HCQIS standards appropriate for the State, what are the technical assistance and educational needs of the system components.

The Medicaid Bureau has already identified a number of such areas; e.g., designing and assessing focused quality of care studies; the appropriate use of outcome measures and clinical practice guidelines; and criteria for continuity of care systems. In addition, the demonstrations and evaluation of the Quality Assurance Reform Initiative which have begun in three States will greatly add to the identification of topics needed to strengthen the capabilities of State Medicaid agencies and other participants of the system in implementing effective health care quality improvement systems. Such areas should be communicated back to the Health Care Financing Administration's Medicaid Bureau so that the Medicaid Bureau can incorporate them into the development of technical assistance and educational programs to assist in the implementation of the QARI.

CHAPTER 1

FRAMEWORK FOR A HEALTH CARE QUALITY IMPROVEMENT SYSTEM FOR RISK-REIMBURSEMENT MEDICAID MANAGED CARE PROGRAMS[1]

I. BACKGROUND

The implementation of managed care within State Medicaid programs directly involves several entities: Medicaid recipients, managed care organizations, State Medicaid agencies and the Federal government (HCFA). If the quality of the health care delivered under Medicaid managed care programs is to be maximized, then the responsibilities of each of these entities as part of an overall Health Care Quality Improvement System (HCQIS) should be clearly delineated and communicated to each. Further, the system should be monitored and assessed on a regular basis to evaluate its effectiveness and efficiency. This chapter describes a framework for such a HCQIS for all State Medicaid managed care programs utilizing HMOs, HIOs, PHPs or other risk-reimbursed managed care providers. The framework addresses both current statutory and regulatory requirements as well as recommended practices for fulfilling these regulatory requirements.

II. PREMISES

A. Quality of health care is defined by the National Academy of Sciences as, "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[2] (underline added) In accordance with this concept, the Medicaid Health Care Quality Improvement System described in this document will address

---

[1] In this document, "managed" care refers to care provided under Medicaid risk contracts with Health Maintenance Organizations (HMOs), Prepaid Health Plans (PHPs) and Health Insuring Organizations (HIOs) that arrange for comprehensive services, and are subject to HMO requirements. When the term "managed care organization (MCO)" is used in this document, it refers to all these forms of risk reimbursed managed care. This manual does not address the Primary Care Case Management (Fee-For-Service) model of managed care, although elements of this proposed system may also be appropriate for such programs.

[2] Institute of Medicine, "Medicare: A Strategy for Quality Assurance," National Academy Press; Washington D.C., 1990.

clinical care and health services delivery issues such as: access to care, utilization of services, and coordination and continuity of care, as opposed to managed care organizational practices which are not normally considered to be "health services;" e.g., insolvency provisions, or physician payment arrangements.

B. Good quality health care can be best promoted by the actual providers of care; i.e., physicians and other health care practitioners who actually deliver the care and thereby have the greatest control over how it is provided. However, as the agent which make these providers available to certain vulnerable populations, the Medicaid program has an obligation to set standards, and monitor and evaluate the provision of health care by the actual providers of the care or the organized systems of care through which these providers deliver care.

C. Federal law requires that Medicaid payment be made directly to the provider of medical services. However, in the case of Medicaid managed care programs, the State Medicaid agency contracts with organizations, (as opposed to individual practitioners) and the provider is considered to be the organization under contract. It is therefore appropriate for the State to require the managed care organization to monitor, evaluate, and take action to address any needed improvements in the quality of health care delivered by all practitioners providing services on its behalf.

The managed care organization should be accountable for monitoring, evaluating, and taking action as necessary to improve the health care delivered or arranged for under its contract with the State, whether it be preventive, primary, specialty, emergency or ancillary care services delivered in in-patient, ambulatory, or home settings. This is true regardless of the arrangement(s) under which practitioners deliver care on behalf of the organization; i.e., staff, group, network, or IPA model of managed care and across all types of risk reimbursed Medicaid managed care organizations; i.e., HMO, HIO, or PHP. This is also true when the organization under contract to the State subcontracts with another or multiple organizations for the provision of care. Regardless of the number of contracting and subcontracting layers between a State's direct contractor and the individual practitioner delivering care under or through that contract, the organization which contracts with the State is responsible for monitoring, evaluating, and taking action as necessary to improve the quality of care delivered by all individual practitioners or organizations providing services to Medicaid enrollees as a result of the contracting organization's agreement with the

State.

D. The Federal government has delegated the responsibility for administering the Medicaid program to States. This includes the responsibility for monitoring the provision of Medicaid services, including those delivered through managed care contracts. In order to fulfill this responsibility with respect to promoting adequate quality of health care, States should: (1) have standards acceptable to the Federal government for what constitutes adequate activities by the managed care organization to promote the provision of good quality health care, and (2) implement effective procedures acceptable to the Federal government for monitoring organizations' adherence to these standards and the actual quality of health care delivered.

E. The Federal government has the responsibility for overseeing State activities. Therefore, with respect to health care quality improvement (QI) for managed care contracts, the Federal role is one of:

1. specifying parameters for acceptable State standards for adequate QI activities to be conducted by State Medicaid managed care programs;

2. defining recommended State practices for monitoring the quality of managed health care; and

3. overseeing State activity in carrying out monitoring responsibilities.

F. As recipients of the medical care provided through Medicaid managed care programs, Medicaid enrollees should also have opportunities to participate in the quality improvement process. The HCQIS should have formal mechanisms for Medicaid enrollees or their representatives to voice recommendations, questions, concerns or grievances.

III. REQUIRED AND RECOMMENDED ELEMENTS OF THE HEALTH CARE QUALITY IMPROVEMENT SYSTEM

ELEMENT A: Internal Quality Assurance Programs

Federal law requires that all managed care organizations contracting with State Medicaid programs under capitation or other risk payment arrangements shall have an internal program of quality assurance. Further, this shall be a term of the contract between the managed care organization and

the State.[3]

It is recommended that States have clear and detailed standards delineating what constitutes an acceptable internal Quality Assurance Program and that these be contained in the contract between the State and the HMO.

Rationale and Guidance to States: There should be an effective and reliable mechanism whereby managed care organizations can monitor, evaluate, and take actions as necessary to improve care rendered by all providers acting on their behalf. Such a mechanism has been developed by leaders in the managed care industry and experts in quality assurance. It is the internal Quality Assurance Program (QAP). Internal QAPs consist of systematic activities, undertaken by the managed care organization itself, to monitor and evaluate the care delivered to its enrollees according to predetermined objective standards, and effect improvements in care, as needed.

If Medicaid managed care is to rely on internal QAPs as a primary vehicle for promoting good quality care, standards should be developed delineating what constitutes an acceptable QAP. Standards for internal QAPs have been developed by a number of organizations. Those most widely acknowledged are promulgated by: The National Committee for Quality Assurance (NCQA); the National Association of HMO Regulators (NAHMOR); and the Health Care Financing Administration (HCFA) (for Federally Qualified HMOs).

HCFA's Medicaid Bureau has developed guidelines for internal QAPs derived from those developed by NCQA, NAHMOR, and HCFA. (See Chapter Two.) These guidelines will be distributed to all States as the first of a number of steps taken by HCFA's Medicaid Bureau in providing technical assistance to States in designing their HCQIS for Medicaid managed care. States may: adopt as standards the guidelines developed by HCFA; add additional State standards to the guidelines to address other quality of care issues of particular concern to itself; or modify the guidelines to develop standards which reflect conditions of particular concern in its own managed care program. In exercising any of these options, States are encouraged to avoid duplicative reviews and to seek consistency with other existing standards as appropriate. At the same time,

---

[3] Current regulatory authority for this requirement is found in Title 42 of the Code of Federal Regulations (CFR) Part 434, section 434.34.

however, it is recommended that all States have formal, written internal QAP standards for managed care organizations with which they contract. It is further recommended that compliance with these standards be a term of the contract between the State and the managed care organization.

ELEMENT B: State Monitoring

States are to monitor each managed care organization to assess to what extent its QAP meets the above State specified standards for internal QAPs. In addition, Federal law requires that States annually assess the quality of health care delivered by the managed care organization. For HMOs and HIOs, Federal law (§1902(a)(30)(C) of the Social Security Act) requires this to be an "annual, independent, external, review of the quality of services delivered." For PHPs this requirement is found in the regulations at 42 CFR 434.53 as an annual medical audit. The regulatory requirement in section 434.53 is considered to be satisfied for HMOs (and HIOs subject to HMO rules) by compliance with section 1902(a)(30)(C).

Rationale and Guidance to States: The internal QAP standards can be effective only to the extent that managed care organizations comply with them. Therefore, States are to have in place effective mechanisms to monitor adherence to them. This, plus the statutory and regulatory requirements cited above for annual quality reviews, require States to perform two different functions to monitor the quality of care delivered by their managed care contractors:

1. States must monitor their managed care contractors to evaluate their compliance with the State's standards for internal QAPs. States may perform this monitoring directly themselves, utilizing Medicaid or other State resources, or they may secure monitoring services through a contractor which is not in a conflict of interest position; e.g., a managed care organization or an association of managed care organizations. Under any approach, States are responsible for being informed of the results of the monitoring and taking action as necessary.

States may develop their own monitoring strategy, following guidelines established by HCFA. States may employ a variety of monitoring approaches; for example, requiring submission to the State of specific data and/or reports on a periodic basis, using on-site monitoring inspections, or a combination of these.

Regardless of the approach(es) used by the State, States should coordinate this monitoring with the required annual EQRO review discussed in Chapter 4, which will provide evidence of the effectiveness of internal QAPs.

2. Under Federal law (Section 1902(a)(30)(C) of the Social Security Act), States are required to contract with one of the following entities to perform an annual "independent, external review of the quality of services furnished under each HMO contract or HIO contract subject to HMO requirements: a Utilization and Quality Control Peer Review Organization (PRO) under contract to the Health Care Financing Administration; an organization which is not currently under contract, but which can meet the requirements for a PRO; or "a private accrediting body." For PHPs, a annual medical audit is required, "to insure that each contractor furnishes quality and accessible health care to enrolled recipients."

In order to maximize the utility of both of these types of quality reviews, they should be coordinated with the managed care organization's internal QAP and be as consistent as possible with similar standards which the organization must meet. Guidelines for fulfilling the "annual, independent, external review" of HMOs and HIOs are found in Chapter Four.

ELEMENT C: Federal Oversight.

The Federal government will continue to monitor States to assure that they are in compliance with Federal laws governing quality of care.

Rationale and Guidance to States: The Federal government has the responsibility for overseeing State activities to assure adherence to Federal law and regulation and Medicaid program requirements governing the operation of the Medicaid program, including managed care programs. Therefore, the Federal government shall monitor States' oversight of HMO, HIO, and PHP managed care programs/contracts to assure that HMOs, HIOs, and PHPs have implemented acceptable QAPs in accordance with the standards in item "B", above. In addition, HCFA will continue to monitor the performance of the "annual, independent, external reviews" for HMOs and HIOs, and the annual medical audits for PHPs.

ELEMENT D: Medicaid Recipient Involvement in the HCQIS

Federal law requires that enrollee/member grievance procedures are instituted at the level of the HMO (42 CFR 434.32) and within the State Medicaid agency (42 CFR 431 Subpart E).

Rationale and Guidance to States: The preceding Federal requirements specify quality improvement actions to be taken by provider organizations and government agencies. There also should be mechanisms that Medicaid recipients can utilize to address their concerns about quality of care issues, including availability and accessibility of services. The State level grievance procedures can be utilized whenever the managed care organization's internal procedures fail to address an enrollee's concerns to the enrollee's satisfaction, or when an enrollee has concerns about an HMO's policy(ies) or practice(es) which the enrollee believes is a hindrance to enrollee health or well being.

However, it is further recommended that attention be paid to involving Medicaid recipients in the oversight process in ways which give them a stronger voice in insuring the availability, accessibility, and acceptability of the health care services they receive. They should have a proactive role as advocates for quality medical care under Medicaid, and their views should be sought on issues central to the improvement of quality of care oversight, such as how quality is measured and effecting desired changes in the provision of medical care.

ELEMENT E: Monitoring and Evaluating the HCQIS

It is recommended that there be a mechanism for formally monitoring, evaluating, and revising the Medicaid managed care Health Care Quality Improvement System and all of its elements on a periodic and regular basis.

Rationale and Guidance to States: Quality Assurance/ Improvement (QA/I) technology is still evolving as a science. If Medicaid Managed Care is to assure that it keeps pace with the developments in QA/QI and the managed care industry, it should implement a process for review and appropriate revision of the HCQIS overall and each of its component elements on a periodic basis.

CHAPTER 2

GUIDELINES FOR INTERNAL QUALITY ASSURANCE PROGRAMS OF HMOs, HIOs AND PHPs CONTRACTING WITH MEDICAID

Federal regulations (42 CFR 434.34) require each Health Maintenance Organization (HMO) and Prepaid Health Plans (PHP), and certain Health Insuring Organizations (HIOs), which contract with State Medicaid agencies, to have in place an internal quality assurance system. Internal Quality Assurance programs (QAPs) consist of systematic activities, undertaken by the managed care organization itself, to monitor and evaluate the care delivered to enrollees according to predetermined, objective standards, and effect improvements as needed. This chapter sets forth guidelines which States may use or modify to establish their own State standards for internal QAPs of their risk-reimbursement Medicaid managed care contractors.

The guidelines were derived from three sources:

- The National Committee for Quality Assurance (NCQA) Quality Assurance Standards, dated June 27, 1991;
- The National Association of HMO Regulators / National Association of Insurance Commissioners' Recommended Operational Requirements for HMO Quality Assurance Programs, adopted by the NAIC/NAHMOR Joint Task Force, December, 1988;
- The HCFA Office of Prepaid Health Care's Quality Assurance Standards for HMOs and CMPs Contracting with the Medicare Program, dated November, 1989;

and were developed under the guidance of a Medical Directors Group representing the managed care industry. While the guidelines contained herein drew upon content from each of these sources, and comments of State Medicaid agencies and other interested parties, they most closely resemble those of the National Committee for Quality Assurance. For parties interested in a direct comparison of these Medicaid guidelines with NCQA's 1993 accreditation standards, see Appendix C.

It is recognized that not all managed care organizations currently meet these Guidelines. Therefore, States are encouraged to work with plans during both the contract negotiation process and ongoing monitoring and evaluation of plan performance, to encourage and support full compliance (or phased-in compliance, if necessary) with those guidelines which the State chooses to adopt.

GUIDELINES FOR INTERNAL QUALITY ASSURANCE PROGRAMS

OF HMOs, HIOs, AND PHPs CONTRACTING WITH MEDICAID

STANDARD I: WRITTEN QAP DESCRIPTION - The organization has a written description of its QAP. This written description meets the following criteria:

A. goals and objectives - The written description contains a detailed set of QA objectives which are developed annually and include a timetable for implementation and accomplishment.

B. scope -

1. The scope of the QAP is comprehensive, addressing both the quality of clinical care and the quality of non-clinical aspects of service, such as and including: availability, accessibility, coordination, and continuity of care.

2. The QAP methodology provides for review of the entire range of care provided by the organization, by assuring that all demographic groups, care settings, (e.g. inpatient, ambulatory, [including care provided in private practice offices] and home care), and types of services (e.g., preventive, primary, specialty care, and ancillary) are included in the scope of the review. (This review of the entire range of care is expected to be carried out over multiple review periods and not on a concurrent basis.)

C. specific activities - The written description specifies quality of care studies and other activities to be undertaken over a prescribed period of time, and methodologies and organizational arrangements to be used to accomplish them. Individuals responsible for the studies and other activities are clearly identified and are appropriate.

D. continuous activity - The written description provides for continuous performance of the activities, including tracking of issues over time.

E. provider review - The QAP provides for:

1. review by physicians and other health professionals of the process followed in the provision of health services; and

2. feedback to health professionals and HMO staff

regarding performance and patient results.

F. **focus on health outcomes** - The QAP methodology addresses health outcomes to the extent consistent with existing technology.

STANDARD II: SYSTEMATIC PROCESS OF QUALITY ASSESSMENT AND IMPROVEMENT - The QAP objectively and systematically monitors and evaluates the quality and appropriateness of care and service to members, through quality of care studies and related activities, and pursues opportunities for improvement on an ongoing basis.

The QAP has written guidelines for its quality of care studies and related activities which include:

A. **specification of clinical or health services delivery areas to be monitored** -

1. The monitoring and evaluation of care reflects the population served by the managed care organization in terms of age groups, disease categories, and special risk status.

2. For the Medicaid population, the QAP monitors and evaluates, at a minimum, care and services in certain priority areas of concern selected by the State. It is recommended that these be taken from among those identified by the Health Care Financing Administration's (HCFA's) Medicaid Bureau and jointly determined by the State and the managed care organization.[4]

3. At its discretion and/or as required by the State Medicaid agency, the organization's QAP also monitors and evaluates other important aspects of care and service.

B. **use of quality indicators** -

Quality indicators are measurable variables relating to a specified clinical or health services delivery area, which are reviewed over a period of time to monitor the process or outcomes of care delivered in that area.

---

[4]For further detail, see Chapter 3, "Clinical and Health Services Delivery Areas of Concern, Quality Indicators, and Clinical Practice Guidelines."

1. The organization identifies and uses quality indicators that are objective, measurable, and based on current knowledge and clinical experience.

2. For the priority areas selected by the State from the HCFA Medicaid Bureau's list of priority clinical and health services delivery areas of concern, the organization monitors and evaluates quality of care through studies which include, but are not limited to, the quality indicators also specified by the HCFA's Medicaid Bureau." [5]

3. Methods and frequency of data collection are appropriate and sufficient to detect need for program change.

C. use of clinical care standards/practice guidelines -

1. The QAP studies and other activities monitor quality of care against clinical care or health service delivery standards or practice guidelines specified for each area identified in "A," above.

2. The standards/guidelines are based on reasonable scientific evidence and are developed or reviewed by plan providers.

3. The standards/guidelines focus on the process and outcomes of health care delivery, as well as access to care.

4. A mechanism is in place for continuously updating the standards/guidelines.

5. The standards/guidelines shall be included in provider manuals developed for use by HMO providers or otherwise disseminated to providers as they are adopted.

6. The standards/guidelines address preventive health services.

7. Standards/guidelines are developed for the full spectrum of populations enrolled in the plan.

8. The QAP shall use these standards/guidelines to

---

[5] For further detail, see Chapter 3, "Clinical and Health ervices Delivery Areas of Concern, Quality Indicators, and linical Practice Guidelines."

evaluate the quality of care provided by the managed care organization's providers, whether the providers are organized in groups, as individuals, as IPAs, or in combinations thereof.

D. analysis of clinical care and related services -

1. Appropriate clinicians monitor and evaluate quality through review of individual cases where there are questions about care, and through studies analyzing patterns of clinical care and related service. For quality issues identified in the QAP's targeted clinical areas, the analysis includes the identified quality indicators and uses clinical care standards or practice guidelines.

2. Multidisciplinary teams are used, where indicated, to analyze and address systems issues.

3. From 1. and 2., clinical and related service areas requiring improvement are identified.

E. implementation of remedial/corrective actions -

The QAP includes written procedures for taking appropriate remedial action whenever, as determined under the QAP, inappropriate or substandard services are furnished, or services that should have been furnished were not.

These written remedial/corrective action procedures include:

1. specification of the types of problems requiring remedial/corrective action;

2. specification of the person(s) or body responsible for making the final determinations regarding quality problems;

3. specific actions to be taken;

4. provision of feedback to appropriate health professionals, providers and staff;

5. the schedule and accountability for implementing corrective actions;

6. the approach to modifying the corrective action if improvements do not occur;

7. procedures for terminating the affiliation with the

physician, or other health professional or provider.

F. **assessment of effectiveness of corrective actions** -

1. As actions are taken to improve care, there is monitoring and evaluation of corrective actions to assure that appropriate changes have been made. In addition, changes in practice patterns are tracked.

2. The managed care organization assures follow-up on identified issues to ensure that actions for improvement have been effective.

G. **evaluation of continuity and effectiveness of the QAP** -

1. The managed care organization conducts a regular and periodic examination of the scope and content of the QAP to ensure that it covers all types of services in all settings, as specified in STANDARD I-B-2.

2. At the end of each year, a written report on the QAP is prepared, which addresses: QA studies and other activities completed; trending of clinical and service indicators and other performance data; demonstrated improvements in quality; areas of deficiency and recommendations for corrective action; and an evaluation of the overall effectiveness of the QAP.

3. There is evidence that QA activities have contributed to significant improvements in the care delivered to members.

STANDARD III: ACCOUNTABILITY TO THE GOVERNING BODY - The Governing Body of the organization is the Board of Directors or, where the Board's participation with quality improvement issues is not direct, a designated committee of the senior management of the managed care organization. Responsibilities of the Governing Body for monitoring, evaluating, and making improvements to care include:

A. **oversight of QAP** - There is documentation that the Governing Body has approved the overall QAP and an annual QA plan.

B. **oversight entity** - The Governing Body has formally designated an accountable entity or entities within the organization to provide oversight of QA, or has formally decided to provide such oversight as a committee of the

whole.

C. **QAP progress reports** - The Governing Body routinely receives written reports from the QAP describing actions taken, progress in meeting QA objectives, and improvements made.

D. **annual QAP review** - The Governing Body formally reviews on a periodic basis (but no less frequently than annually) a written report on the QAP which includes: studies undertaken, results, subsequent actions, and aggregate data on utilization and quality of services rendered, to assess the QAP's continuity, effectiveness and current acceptability.

E. **program modification** - Upon receipt of regular written reports from the QAP delineating actions taken and improvements made, the Governing Body takes action when appropriate and directs that the operational QAP be modified on an ongoing basis to accommodate review findings and issues of concern within the managed care organization (MCO). This activity is documented in the minutes of the meetings of the Governing Board in sufficient detail to demonstrate that it has directed and followed up on necessary actions pertaining to Quality Assurance.

STANDARD IV: ACTIVE QA COMMITTEE - The QAP delineates an identifiable structure responsible for performing QA functions within the MCO. This committee or other structure has:

A. **regular meetings** - The structure/committee meets on a regular basis with specified frequency to oversee QAP activities. This frequency is sufficient to demonstrate that the structure/committee is following-up on all findings and required actions, but in no case are such meetings less frequent than quarterly.

B. **established parameters for operating** - The role, structure and function of the structure/committee are specified.

C. **documentation** - There are records documenting the structure's/committee's activities, findings, recommendations and actions.

D. **accountability** - The QAP committee is accountable to the Governing Body and reports to it (or its designee) on a scheduled basis on activities, findings, recommendations and actions.

E. **membership** - There is active participation in the QA committee from health plan providers, who are representative of the composition of the health plan's providers.

STANDARD V: QAP SUPERVISION - There is a designated senior executive who is responsible for program implementation. The organization's Medical Director has substantial involvement in QA activities.

STANDARD VI: ADEQUATE RESOURCES - The QAP has sufficient material resources; and staff with the necessary education, experience, or training; to effectively carry out its specified activities.

STANDARD VII: PROVIDER PARTICIPATION IN THE QAP -

A. Participating physicians and other providers are kept informed about the written QA plan.

B. The MCO includes in <u>all</u> its provider contracts and employment agreements, for both physicians and non-physician providers, a requirement securing cooperation with the QAP.

C. Contracts specify that hospitals and other contractors will allow the managed care organization access to the medical records of its members.

STANDARD VIII: DELEGATION OF QAP ACTIVITIES - The MCO remains accountable for all QAP functions, even if certain functions are delegated to other entities. If the managed care organization delegates any QA activities to contractors:

A. There is a written description of: the delegated activities; the delegate's accountability for these activities; and the frequency of reporting to the managed care organization.

B. The MCO has written procedures for monitoring and evaluating the implementation of the delegated functions and for verifying the actual quality of care being provided.

C. There is evidence of continuous and ongoing evaluation of delegated activities, including approval of quality improvement plans and regular specified reports.

STANDARD IX: CREDENTIALING AND RECREDENTIALING - The QAP contains the following provisions to determine whether physicians and other health care professionals, who are licensed by the State and who are under contract to the MCO, are qualified to perform their services.

A. **written policies and procedures** - The managed care organization has written policies and procedures for the credentialing process, which includes the organization's initial credentialing of practitioners, as well as its subsequent recredentialing, recertifying and/or reappointment of practitioners.

B. **oversight by Governing body** - The Governing Body, or the group or individual to which the Governing Body has formally delegated the credentialing function, has reviewed and approved the credentialing policies and procedures.

C. **credentialing entity** - The plan designates a credentialing committee or other peer review body which makes recommendations regarding credentialing decisions.

D. **scope** - The plan identifies those practitioners who fall under its scope of authority and action. This shall include, at a minimum, all physicians, dentists, and other licensed independent practitioners included in the review organization's literature for members, as an indication of those practitioners whose service to members is contracted or anticipated.

E. **process** - The initial credentialing process obtains and reviews verification of the following information, at a minimum:

1. the practitioner holds a current valid license to practice;

2. valid DEA or CDS certificate, as applicable;

3. graduation from medical school and completion of a residency, or other post-graduate training, as applicable;

4. work history;

5. professional liability claims history;

6. good standing of clinical privileges at the hospital designated by the practitioner as the primary admitting facility; (This requirement may be waived for practices

which do not have or do not need access to hospitals.)

7. the practitioner holds current, adequate malpractice insurance according to the plan's policy;

8. any revocation or suspension of a state license or DEA/BNDD number;

9. any curtailment or suspension of medical staff privileges (other than for incomplete medical records);

10. any sanctions imposed by Medicare and/or Medicaid; and

11. any censure by the State or County Medical Association.

12. The organization requests information on the practitioner from the National Practitioner Data Bank and the State Board of Medical Examiners.

13. The application process includes a statement by the applicant regarding:

a. any physical or mental health problems that may affect current ability to provide health care;

b. any history of chemical dependency/substance abuse;

c. history of loss of license and/or felony convictions;

d. history of loss or limitation of privileges or disciplinary activity; and

e. an attestation to correctness / completeness of the application.

This information should be used to evaluate the practitioners's current ability to practice.

14. There is an initial visit to each potential primary care practitioners's office, including documentation of a structured review of the site and medical recordkeeping practices to ensure conformance with the managed care organization's standards.

F. recredentialing - A process for the periodic reverification of clinical credentials (recredentialing, reappointment, or recertification) is described in the organization's policies and procedures.

1. There is evidence that the procedure is implemented at least every two years.

2. The MCO conducts periodic review of information from the National Practitioner Data Bank, along with performance data, on all physicians, to decide whether to renew the participating physician agreement. At a minimum, the recredentialing, recertification or reappointment process is organized to verify current standing on items listed in "E-1" through "E-7", above and item "E-13" as well.

3. The recredentialing, recertification or reappointment process also includes review of data from:

a. member complaints;

b. results of quality reviews;

c. utilization management;

d. member satisfaction surveys; and

e. reverification of hospital privileges and current licensure.

G. **delegation of credentialing activities** - If the managed care organization delegates credentialing (and recredentialing, recertification, or reappointment) activities, there is a written description of the delegated activities, and the delegate's accountability for these activities. There is also evidence that the delegate accomplished the credentialing activities. The managed care organization monitors the effectiveness of the delegate's credentialing and reappointment or recertification process.

H. **retention of credentialing authority** - The managed care organization retains the right to approve new providers and sites, and to terminate or suspend individual providers. The organization has policies and procedures for the suspension, reduction or termination of practitioner privileges.

I. **reporting requirement** - There is a mechanism for, and evidence of implementation of, the reporting of serious quality deficiencies resulting in suspension or termination of a practitioner, to the appropriate authorities.

J. **appeals process** - There is a provider appellate process

for instances where the managed care organization chooses to reduce, suspend or terminate a practitioner's privileges with the organization.

STANDARD X: ENROLLEE RIGHTS AND RESPONSIBILITIES - The organization demonstrates a commitment to treating members in a manner that acknowledges their rights and responsibilities.

A. written policy on enrollee rights - The organization has a written policy that recognizes the following rights of members:

1. to be treated with respect, and recognition of their dignity and need for privacy;

2. to be provided with information about the organization, its services, the practitioners providing care, and members rights and responsibilities;

3. to be able to choose primary care practitioners, within the limits of the plan network, including the right to refuse care from specific practitioners;

4. to participate in decision-making regarding their health care;

5. to voice grievances about the organization or care provided;

6. to formulate advance directives; and

7. to have access to his/her medical records in accordance with applicable Federal and State laws.

B. written policy on enrollee responsibilities - The organization has a written policy that addresses members' responsibility for cooperating with those providing health care services. This written policy addresses members' responsibility for:

1. providing, to the extent possible, information needed by professional staff in caring for the member; and

2. following instructions and guidelines given by those providing health care services.

C. communication of policies to providers - A copy of the organization's policies on members' rights and responsibilities is provided to all participating providers.

D. **communication of policies to enrollees/members** - Upon enrollment, members are provided a written statement that includes information on the following:

1. rights and responsibilities of members;

2. benefits and services included and excluded as a condition of membership, and how to obtain them, including a description of:

a. any special benefit provisions (for example, co-payment, higher deductibles, rejection of claim) that may apply to service obtained outside the system; and

b. the procedures for obtaining out-of-area coverage;

3. provisions for after-hours and emergency coverage;

4. the organization's policy on referrals for specialty care;

5. charges to members, if applicable, including:

a. policy on payment of charges; and

b. co-payment and fees for which the member is responsible;

6. procedures for notifying those members affected by the termination or change in any benefits, services, or service delivery office/site.

7. procedures for appealing decisions adversely affecting the members's coverage, benefits, or relationship to the organization;

8. procedures for changing practitioners;

9. procedures for disenrollment; and

10. procedures for voicing complaints and/or grievances and for recommending changes in policies and services.

E. **enrollee/member grievance procedures** - The organization has a system(s), linked to the QAP, for resolving members' complaints and formal grievances. This system includes:

1. procedures for registering and responding to complaints and grievances in a timely fashion

(organizations should establish and monitor standards for timeliness);

2. documentation of the substance of complaints or grievances, and actions taken;

3. procedures to ensure a resolution of the complaint or grievance;

4. aggregation and analysis of complaint and grievance data and use of the data for quality improvement; and

5. an appeal process for grievances.

F. enrollee/member suggestions - Opportunity is provided for members to offer suggestions for changes in policies and procedures.

G. steps to assure accessibility of services - The managed care organization takes steps to promote accessibility of services offered to members. These steps include:

1. The points of access to primary care, specialty care, and hospital services are identified for members.

2. At a minimum, members are given information about:

a. how to obtain services during regular hours of operations;

b. how to obtain emergency and after-hours care; and

c. how to obtain the names, qualifications, and titles of the professionals providing and/or responsible for their care.

H. written information for members -

1. Member information (for example, subscriber brochures, announcements, handbooks) is written in prose that is readable and easily understood.

2. Written information is available, as needed, in the languages of the major population groups served. A "major" population group is one which represents at least 10% of a plan's membership.

I. confidentiality of patient information - The organization acts to ensure that the confidentiality of specified patient information and records is protected.

1. The organization has established in writing, and enforced, policies and procedures on confidentiality, including confidentiality of medical records.

2. The organization ensures that patient care offices/sites have implemented mechanisms that guard against the unauthorized or inadvertent disclosure of confidential information to persons outside of the medical care organization.

3. The organization shall hold confidential all information obtained by its personnel about enrollees related to their examination, care and treatment and shall not divulge it without the enrollee's authorization, unless:

a. it is required by law;

b. it is necessary to coordinate the patient's care with physicians, hospitals, or other health care entities, or to coordinate insurance or other matters pertaining to payment; or

c. it is necessary in compelling circumstances to protect the health or safety of an individual.

4. Any release of information in response to a court order is reported to the patient in a timely manner.

5. Enrollee records may be disclosed, whether or not authorized by the enrollee, to qualified personnel for the purpose of conducting scientific research, but these personnel may not identify, directly or indirectly, any individual enrollee in any report of the research or otherwise disclose participant identity in any manner.

J. **treatment of minors** - The organization has written policies regarding the appropriate treatment of minors.

K. **assessment of member satisfaction** - The organization conducts periodic surveys of member satisfaction with its services.

1. The surveys include content on perceived problems in the quality, availability, and accessibility of care.

2. The surveys assess at least a sample of:

a. all Medicaid members;

b. Medicaid member requests to change

practitioners and/or facilities; and

c. disenrollment by Medicaid members.

3. As a result of the surveys, the organization:

a. identifies and investigates sources of dissatisfaction;

b. outlines action steps to follow-up on the findings; and

c. informs practitioners and providers of assessment results.

4. The organization reevaluates the effects of the above activities.

STANDARD XI: STANDARDS FOR AVAILABILITY AND ACCESSIBILITY - The MCO has established standards for access (e.g., to routine, urgent and emergency care; telephone appointments; advice; and member service lines). Performance on these dimensions of access are assessed against the standards.

STANDARD XII: MEDICAL RECORD STANDARDS -

A. accessibility and availability of medical records -

1. The MCO shall include provisions in provider contracts for appropriate access to the medical records of its enrollees for purposes of quality reviews conducted by the Secretary, State Medicaid agencies, or agents thereof.

2. Records are available to health care practitioners at each encounter.

B. recordkeeping Medical records may be on paper or electronic. The Plan takes steps to promote maintenance of medical records in a legible, current, detailed, organized and comprehensive manner that permits effective patient care and quality review as follows:

1. medical record standards - The organization sets standards for medical records. The records reflect all aspects of patient care, including ancillary services. These standards shall, at a minimum, include requirements for:

a. patient identification information - Each page or electronic file in the record contains the patient's name or patient ID number.

b. personal/biographical data - Personal/ biographical data includes: age; sex; address; employer; home and work telephone numbers; and marital status.

c. entry date - All entries are dated.

d. provider identification - All entries are identified as to author.

e. legibility - The record is legible to someone other than the writer. Any record judged illegible by one physician reviewer should be evaluated by a second reviewer.

f. allergies - Medication allergies and adverse reactions are prominently noted on the record. Absence of allergies (no known allergies -- NKA) is noted in an easily recognizable location.

g. past medical history - (for patients seen 3 or more times) Past medical history is easily identified including serious accidents, operations, illnesses. For children, past medical history relates to prenatal care and birth.

h. immunizations - for pediatric records (ages 12 and under) there is a completed immunization record or a notation that immunizations are up-to-date.

i. diagnostic information

j. medication information

k. identification of current problems - Significant illnesses, medical conditions and health maintenance concerns are identified in the medical record.

l. smoking/ETOH/substance abuse - Notation concerning cigarettes and alcohol use and substance abuse is present. (For patients 12 years and over and seen 3 or more times.) Abbreviations and symbols may be appropriate.

m. consultations, referrals and specialist reports

- Notes from any consultations are in the record. Consultation, lab, and x-ray reports filed in the chart have the ordering physician's initials or other documentation signifying review. Consultation and significantly abnormal lab and imaging study results have an explicit notation in the record of follow-up plans.

n. emergency care

o. hospital discharge summaries - discharge summaries are included as part of the medical record for: (1) all hospital admissions which occur while the patient is enrolled in the MCO and (2) prior admissions as necessary.

p. advance directive - For medical records of adults, the medical record documents whether or not the individual has executed an advance directive. An advance directive is a written instruction such as a living will or durable power of attorney for health care relating to the provision of health care when the individual is incapacitated.

2. patient visit data - documentation of individual encounters must provide adequate evidence of, at a minimum:

a. History and physical examination - Appropriate subjective and objective information is obtained for the presenting complaints.

b. plan of treatment;

c. diagnostic tests;

d. therapies and other prescribed regimens;

e. follow-up - Encounter forms or notes have a notation, when indicated, concerning follow-up care, call or visit. Specific time to return is noted in weeks, months, or PRN. Unresolved problems from previous visits are addressed in subsequent visits.

f. referrals and results thereof; and

g. all other aspects of patient care, including ancillary services.

C. **record review process** -

1. The MCO has a system (record review process) to assess the content of medical records for legibility, organization, completion and conformance to its standards.

2. The record assessment system addresses documentation of the items listed in B, above.

STANDARD XIII: UTILIZATION REVIEW -

A. **written program description** - The organization has a written utilization management program description which includes, at a minimum, procedures to evaluate medical necessity, criteria used, information-sources and the process used to review and approve the provision of medical services.

B. **scope** - The program has mechanisms to detect underutilization as well as overutilization.

C. **preauthorization and concurrent review requirements** - For organizations with preauthorization or concurrent review programs:

1. Preauthorization and concurrent review decisions are supervised by qualified medical professionals.

2. Efforts are made to obtain all necessary information, including pertinent clinical information, and consult with the treating physician as appropriate.

3. The reasons for decisions are clearly documented and available to the member.

4. There are well-publicized and readily available appeals mechanisms for both providers and patients. Notification of a denial includes a description of how to file an appeal.

5. Decisions and appeals are made in a timely manner as required by the exigencies of the situation.

6. There are mechanisms to evaluate the effects of the program using data on member satisfaction, provider satisfaction or other appropriate measures.

7. If the organization delegates responsibility for

utilization management, it has mechanisms to ensure that these standards are met by the delegate.

STANDARD XIV: CONTINUITY OF CARE SYSTEM - The MCO has put a basic system in place which promotes continuity of care and case management.

STANDARD XV: QAP DOCUMENTATION -

A. **scope** - The MCO shall document that it is monitoring the quality of care across all services and all treatment modalities, according to its written QAP. (This review of the entire range of care is expected to be carried out over multiple review periods and not on a concurrent basis.)

B. **maintenance and availability of documentation** - The MCO must maintain and make available to the State, and upon request to the Secretary, studies, reports, protocols, standards, worksheets, minutes, or such other documentation as may be appropriate, concerning its QA activities and corrective actions.

STANDARD XVI: COORDINATION OF QA ACTIVITY WITH OTHER MANAGEMENT ACTIVITY - The findings, conclusions, recommendations, actions taken, and results of the actions taken as a result of QA activity, are documented and reported to appropriate individuals within the organization and through the established QA channels.

A. QA information is used in recredentialing, recontracting and/or annual performance evaluations.

B. QA activities are coordinated with other performance monitoring activities, including utilization management, risk management, and resolution and monitoring of member complaints and grievances.

C. There is a linkage between QA and the other management functions of the health plan such as:

1. network changes;

2. benefits redesign

3. medical management systems (e.g. pre-certification);

4. practice feedback to physicians;

5. patient education; and

6. member services.

CHAPTER 3

CLINICAL AND HEALTH SERVICES DELIVERY AREAS OF CONCERN, QUALITY INDICATORS, AND CLINICAL PRACTICE GUIDELINES

I. INTRODUCTION:

Chapter 2, "Guidelines for Internal Quality Assurance Programs of HMOs, HIOs, and PHPs Contracting With Medicaid" (the Guidelines) described the activities which the Medicaid Bureau recommends as standards for internal quality assurance programs (QAPs). The Guidelines, in part, call for managed care organizations to implement a systematic process of quality assessment and improvement by which the care delivered to enrollees is monitored, evaluated, and continually improved. The guidelines further recommend that managed care organizations conduct quality of care studies which:

A. target specific clinical conditions; e.g., pregnancy, and/or specific health services delivery issues; e.g., access to care, for focused monitoring and evaluation;

B. use clinical care standards/practice guidelines to objectively evaluate the care the organization delivers (or fails to deliver) for the targeted clinical conditions and health services delivery issues; and

C. use quality indicators derived from the clinical care standards/practice guidelines to screen and monitor care and services delivered.

This chapter provides further recommendations for how these three activities can be implemented by managed care organizations under the Guidelines for internal QAPs.

In implementing these activities, appropriate flexibility will be needed to accommodate the varying data collection and monitoring systems currently in place within managed care organizations and the differing requests from other purchasers to which the organization must respond. In addition, States should identify any technical assistance and education needs which they or their managed care contractors have in this area. These technical assistance/ education/ data interpretation needs should be forwarded to HCFA's Medicaid Bureau to inform the Medicaid Bureau of priority training needs of State Medicaid Agencies in quality assessment and improvement.

II. QUALITY OF CARE STUDIES:

A managed care organization cannot monitor the care delivered to every enrollee each time he or she requires health care. Such an attempt would be beyond the organization's and State and Federal resources. As an alternative, managed care organizations generally select certain aspects of care to monitor over a specified time period. Over subsequent time periods, monitoring may be repeated in that area to detect patterns of care over time, or the organization may select new areas to monitor. Such monitoring takes place through focused quality of care studies.

Focused quality of care studies are detailed investigations of certain aspects of health care services which are designed to answer defined questions about the quality and appropriateness of care and point the way to how that care can be improved. Such focused studies are superior to random or unfocused record reviews because they provide information about care in the aggregate as opposed to information about the care received by a limited number of enrollees.

A focused study may be conducted by reviewing medical records, by reviewing claims or other administrative data, by conducting special surveys, or other mechanisms. Whatever the source of information, all well designed studies have the following components:

A. A clearly defined study question which focuses on relevant areas of concern in health care. - Quality of care studies may be small and narrowly focused; e.g., "When are pregnant enrollees receiving their first prenatal care visits?" or, large and more complex e.g., "What prenatal care factors are associated with enrollees delivering low birth weight babies? The size, scope, and sophistication of quality of care studies are often a reflection of the age, size and sophistication of the managed care organization, in addition to the organization's commitment to quality improvement. However, regardless of the complexity of the study, the clinical areas selected for study should reflect the managed care organization's enrollment in terms of demographic characteristics and the prevalence or risk of disease, and reflect the potential consequence of the (risk of) disease.

B. Well defined items (clinical indicators) to be monitored and evaluated to help answer the question.

C. A standard or standards against which the organization compares itself.

D. A method for analyzing the results to indicate ways in

identification of pregnancy and childhood immunizations as recommended areas for continuous monitoring and evaluation by managed care plans, the areas listed below are not listed in any order of priority. States can best determine the priority clinical and health services delivery areas to be monitored and reported upon by their managed care contractors.

In determining the areas to be monitored by its managed care contractors, States should recognize that HMOs respond to similar requests from a variety of purchasers for data on the services rendered to their enrollee groups. As a result, plans should not be expected to conduct an unlimited number of studies or mount an unlimited number of data collection efforts.

Further, there are efforts underway to coordinate State, Federal and private purchaser data requests. However, until that happens, it is important to realize that a successful internal quality assurance system can yield plan wide benefits which are not limited to any one enrollee group. States should work with managed care organizations to develop coordinated requirements.

Clinical Areas of Concern:

1. Childhood Immunizations (Recommended for requirement)
2. Pregnancy (Recommended for requirement)
3. Breast Cancer / Mammography
4. Cervical Cancer / Pap Smears
5. Lead toxicity
6. Comprehensive Well Child Periodic Health Assessment
7. HIV status
8. Asthma
9. Hysterectomies
10. Diabetes

"Guide to Clinical Preventive Services: An Assessment of the Effectiveness of 169 Interventions: Report of the U.S. Preventive Services Task Force, "William and Wilkins, Baltimore, Maryland 1989; and "Albert 1. Siu, et al, "Choosing Quality of Care Measures Based on the Expected Impact of Improved Care on Health" Health Services Research 27:5, December 1992.

11. ETOH and Other Substance Abuse
12. Hypertension
13. Sexually Transmitted Diseases
14. Heritable Diseases (newborn screens)
15. Coronary Artery Disease
16. Motor Vehicle Accidents
17. Pregnancy prevention
18. Tuberculosis
19. Sickle Cell Anemia
20. Failure to thrive
21. Hepatitis B
22. Otitis Media
23. Mental health
24. Prescription Drug Abuse
25. Hip Fractures
26. Cholesterol Screening and Management
27. Treatment of Myocardial Infarctions
28. Prevention of Influenza
29. Smoking Prevention and Cessation
30. Medical Problems of the Frail Elderly; e.g., incontinence and confusion
31. Hearing and Vision Screening and Services for Individuals Less Than 21 Years of Age
32. Dental Screening and Services for Individuals Less Than 21 Years of Age
33. Domestic Violence

Health Services Delivery Areas of Concern:

1. access to care
2. utilization of services
3. coordination of care
4. continuity of care
5. health education
6. emergency services

Two of the clinical areas of concern (childhood immunizations and pregnancy) are recommended to be, "required" of managed care contractors by State Medicaid agencies because of their critical importance. They are recommended here for continuous evaluation and study by all managed care organizations unless those organizations serve a predominantly or exclusively non-AFDC Medicaid population; e.g., the elderly or disabled. It is recommended that plans additionally select, on an annual basis, at least one other clinical or health service delivery area of concern, at their own discretion or as directed by the State, to be the focus of additional clinical study(ies). Plans may monitor care and service for greater numbers of these areas: (1) as undertaken as part of their own internal QAP agenda, and/or (2) as directed by the State.

IV. CLINICAL PRACTICE GUIDELINES/STANDARDS:

The identification of areas needing improvement and the creation of a baseline for future assessment necessitates specifying goals or standards for health services to which care actually delivered can be compared. STANDARD II-C in the Guidelines states, in part, that:

> 1. The QAP studies and other activities monitor quality of care against clinical care or health services delivery standards or practice guidelines specified for each clinical or health services delivery area to be monitored.

Clinical care standards, practice guidelines, practice options and practice advisories are all types of "practice parameters." Practice parameters are recommendations or an agreed upon set of principles for the delivery of certain types or aspects of health care. They are promulgated by authoritative bodies such as professional associations or ad-hoc "expert committees". Because professional judgement may often vary, there can frequently be more than one set of practice parameters addressing the same

topic. However, the vast majority of medical professional organizations endorse the use of practice parameters in improving the quality of medical care.

For this reason, the Guidelines recommend monitoring quality of care using clinical care standards or practice guidelines. As an example, for the Federally recommended clinical areas of pregnancy and childhood immunizations, commonly accepted sources of guidelines are:

- The American Academy of Pediatrics (AAP);
- The U.S. Department of Health and Human Services' Public Health Service (PHS); and
- The American College of Obstetricians and Gynecologists (ACOG).

For other clinical or health services delivery areas to be studied by the managed care organization as part of its agreement with the State Medicaid agency, the State and the managed care organization should agree upon the clinical practice standards or practice guidelines which are to be utilized by the organization in its evaluation of care.[7]

V. QUALITY INDICATORS:

In conducting quality of care studies, the organization assesses care through the use of objective indicators. Quality indicators are measurable variables relating to a specified clinical or health services delivery area, which are reviewed over a period of time to screen delivered health care and/or to monitor the process or outcome of care delivered in that clinical area. STANDARD II-B of the Guidelines states:

> "1. The organization identifies and uses quality indicators that are objective, measurable, and based on current knowledge and clinical experience.
>
> 2. For the priority areas selected by the State from the HCFA Medicaid Bureau's list of priority clinical and health services delivery areas of concern, the organization monitors and evaluates quality of care through studies which

---

[7] A compilation of practice parameters can be found in the American Medical Association's annual publication and quarterly updates, "Directory of Practice Parameters," American Medical Association; Chicago Illinois. In addition, HCFA's Medicaid Bureau is compiling a list of practice parameters for the clinical areas of concern identified here.

include, but are not limited to, the quality indicators also specified by the HCFA's Medicaid Bureau."

The State and the managed care organization should mutually determine clinical indicators to be monitored for each clinical or health services delivery area of concern to be monitored for the Medicaid population. A State may choose to utilize the following recommended clinical indicators for the priority areas of pregnancy and immunizations or it may choose to develop others. Because of their importance, it is recommended that pregnancy and immunization indicators be monitored on a continuous basis by the organization (as opposed to on a one time basis) and periodically (not less than annually) reported to the State. At its own discretion or as directed by the State, the organization should identify, based on clinical practice guidelines described above, additional clinical indicators to be monitored for the additionally selected clinical conditions.

States should recognize that managed care organizations have differing systems in place to conduct this type of monitoring and that the monitoring indicators specified for childhood immunizations and pregnancy may not currently be able to be provided by all plans. Because of this, States may need to work closely with their Medicaid managed care contractors to develop the best means of accomplishing desired oversight in areas of special interest to the Medicaid population. In doing so, States should take into consideration the current ability of managed care plans to carry out a particular methodology, resources needed for compliance, the degree of patient cooperation and other constraints faced by plans, and the need to coordinate data requests from numerous purchasers.

Recommended Clinical Indicators:

A. CHILDHOOD IMMUNIZATIONS

Clinical Indicators: For Medicaid enrollees who are two years of age:

- the rates of receipt of all recommended immunizations against polio (OPV), diphtheria-tetanus-pertussis (DTP), measles-mumps-rubella (MMR), and hepatitis B (HBV) in the first two years of life; and

- the rate of receipt of at least one Haemophilus influenza type B vaccine in the second year of life

(during months 13 through 24).[8]

Methodology for Monitoring and Reporting Indicators:

1. Identify all Medicaid enrollees who were or attained two years of age in the twelve month review period and who were enrolled in the plan for at least six (6) consecutive months of the 12 month review period.

Report this number: _____ and the dates of the twelve month review period: from _____ to _____.

2. Randomly sample and review the medical records or other immunization data source of the organization for at least one hundred (100) of the above enrollees. For each enrollee, record the presence or absence of receipt of the full complement of OPV, DTP, MMR, and HBV immunizations (and the single dose of HIB to be administered in the second year of life) according to the American Academy of Pediatricians or U.S. Center for Disease Control Advisory Committee on Immunization Practices' standards for immunizations prior to age two.

---

[8] Although a standard can be set for the exact number of OPV, DTP, MMR and HBV immunizations a child is to receive in the first two years of life, in the case of H influenza type B, ascertaining whether a health plan's two year olds have received the recommended number of doses of H influenza type B vaccine is complicated by a 1991 transition to a new recommended immunization schedule for HIB and the fact that the number of recommended doses varies depending upon the vaccine product being used. We do know, however, that all children should receive at least one dose during their second year of life. Therefore, these immunization indicators will assess the rate of receipt of the HIB immunization in the second year of life as a proxy for receipt of all prior H influenza type B immunizations.

3. For each of the above immunizations, calculate the organization's rate of immunization as in the following example:

Polio immunizations:

Number of enrollees receiving all three polio immunization doses:

	Number	Percent
From plan: *	_____	_____
By out-of-plan provider: *	_____	_____
Documented refusal by parent or guardian:	_____	_____
Medical contraindications: specify cause:_____	_____	_____
Two attempts to contact:	_____	_____
Other; i.e., lack of any or all immunizations, failure to document; et.al.,:	_____	_____
TOTAL	n	%

* If an enrollee receives the three doses of the immunization from both the Plan and out-of-plan provider(s), record it under the category which was most frequently used.

Immunization Rate for polio = x/n
where x equals the number of Medicaid children in the sample fully immunized, either by plan or out-of-plan providers, and n = sample size.

Adjusted polio immunization rate = y/n
where y equals the sum of Medicaid children in the sample immunized (i.e., the variable x above), plus Medicaid sample children for whom there were two documented attempts to notify parents of need, documented refusal, or medical contraindications to immunizations.

4. Repeat the above steps for the required four DTP, one MMR, and three HBV immunizations to be given in the first two years of life, and single HIB immunization to be given in the second year of life.

B. PREGNANCY

Indicators and Methodology for Measuring Indicators:

1. Identify all Medicaid enrollees who delivered single or multiple live or stillborn fetus(es) of greater than or equal to 20 weeks gestation for the most recent twelve month reporting period. Report:

   a. The number of such enrollees: _____

   b. The number of fetuses of at least 20 weeks gestation delivered: _____

   c. The dates of the reporting period: from _____ to _____.

2. Report the following information for all such enrollees or a <u>randomly selected</u> sample of at least one hundred (100) of these enrollees:

   a. The timing of the enrollee's enrollment in the MCO with respect to each pregnancy:

   - preconception _____
   - first trimester _____
   - second trimester _____
   - third trimester _____

   b. The weeks of gestation on the date of the first prenatal care visit:_____. If date of delivery is date of first contact related to pregnancy, indicate as "no prenatal care."

   c. Number of prenatal care visits from and including the first prenatal care visit to and including the last visit prior to delivery: _____

   d. Pregnancy outcome:

   - fetal loss (≥ 20 weeks) _____
   - live birth _____

   e. Birth weight for each live birth:

   - <500 Gms. _____
   - 500 - 1499 Gms. _____
   - 1500 - 2499 Gms. _____
   - ≥ 2500 Gms. _____

CHAPTER 4

GUIDELINES FOR EXTERNAL QUALITY REVIEW

I. INTRODUCTION:

Federal law (Section 1902(a)(30)(C) of the Social Security Act) requires entities which are external to and independent of the State and its HMO and HIO contractors to perform, on an annual basis, a review of the quality of services furnished by each such contractor.[9] Although this law specifies the types of entities which are allowed to perform this annual quality review, it does not prescribe how this quality review is to be conducted. This chapter specifies a recommended scope of work for external quality review organization (EQRO) review of health care and services provided by HMOs and HIOs to their Medicaid enrollees.

External review can help to validate the success or identify the shortcomings of the HMO's/HIO's internal quality assurance systems. However, it is important that States, in exercising their responsibility for assuring contractor compliance with requirements for internal quality assurance systems, construct internal QAP oversight and external review to complement rather than duplicate each other. Reviews conducted by States and external review organizations should be coordinated with each other, and where possible, with other reviews to which HMOs/ HIOs are subject. States, EQROs and HMOs/HIOs should work in close cooperation to insure workable implementation of external review.

Also, State and HIO/HMO personnel, in addition to EQRO personnel, will need a thorough understanding of the epidemiologic and statistical measurement of health status indicators in defined populations, including the scope and methodology of data collection, the interpretation of the data and an understanding of the social and economic factors that affect the interpretation of the data.

---

[9] This requirement governs only HMOs and HIOs. PHPs are subject to a requirement for a "medical audit" which may be conducted by the State itself. This chapter addresses only the external quality review requirement for HMOs and HIOs, although the principles discussed herein also have applicability to the conduct of periodic medical audits of PHPs. When the term "plan" or "managed care organization" is used in this section it refers only to HMOs and HIOs, and not to PHPs.

II. **PURPOSE:**

The purpose of the external review function should be twofold:

- TO PROVIDE STATES AND THE FEDERAL GOVERNMENT WITH AN INDEPENDENT ASSESSMENT OF THE QUALITY OF HEALTH CARE DELIVERED TO MEDICAID RECIPIENTS ENROLLED IN MEDICAID CONTRACTING HMOs AND HIOs.

- TO RESOLVE IDENTIFIED PROBLEMS IN HEALTH CARE AND CONTRIBUTE TO IMPROVING THE CARE OF ALL MEDICAID RECIPIENTS ENROLLED IN MEDICAID CONTRACTING HMOs AND HIOs.

In order to accomplish these objectives, the information produced by the EQRO review should meet the following criteria:

A. Information should accurately and reliably describe the care delivered to Medicaid recipients. - Information on quality of care obtained from the independent external review is a critical component of the Medicaid Quality Improvement System (QIS) for managed care. If the QIS is to be effective in improving care, it must have accurate and reliable information upon which the State and the HMO/HIO can take action to improve care. Therefore, reviews of care should be conducted in accordance with generally accepted principles of research design and statistical analysis in order to produce valid, reliable, and generalizable information.

B. Information should have the largest possible impact on care. - Because resources are finite, it is not possible to examine every episode of illness or every encounter with a provider for every Medicaid enrollee. Therefore, the external quality review should give priority attention to clinical conditions or health services delivery issues:

- which have highest prevalence or incidence; and

- for which appropriate care has the greatest potential for improving health outcomes.

C. Information should clearly identify instances in which care can be improved and provide a baseline for future assessment to see if care has actually been improved. - The identification of areas needing improvement and the creation of a baseline for future assessment requires the advance specification of goals or standards for health services to which care actually delivered can be compared. The external quality review should measure care delivered against objective measures of health care which have been agreed

upon, to the extent possible, by the State, the EQRO, and the HMOs/HIOs. However, final authority for the selection of these measures rests with the State.

In order to secure external quality reviews which are consistent with these criteria, it is recommended that States adhere to the following guidelines for contracting for, designing, and implementing external quality reviews.

III. CONCEPTUAL APPROACH:[10] (Note: Implementation Issues are Addressed in Section IV)

External Quality Review should include three types of activities:

A. focused studies of patterns of care;

B. individual case review in specific situations; and

C. follow-up activities on previous pattern of care study findings and individual case review findings.

Each of these activities is described below. The appropriate roles of State Medicaid agencies, EQROs and HMOs/HIOs in carrying out these activities are discussed in section IV, Implementation.

A. Focused Pattern of Care Studies

Focused pattern of care studies are detailed investigations of certain aspects of care for specific clinical areas of interest; e.g., pregnancy, asthma, or immunizations, or for defined aspects of health services delivery which cut across clinical areas; e.g., access to care, utilization of services, coordination of care, continuity of care, health education or emergency services.

---

[10] State Medicaid agencies are responsible for monitoring managed care contractors' adherence to, "Guidelines for Internal Quality Assurance Programs of HMOs, HIOs and PHPs Contracting with Medicaid." States may conduct this monitoring either directly themselves or through a contractor which may or may not be the same as the EQRO. The specifications for external review contained herein do not address this required monitoring of the structure and operation of a plan's internal Quality Assurance program, although this function may be independently delegated to the EQRO by the State Medicaid agency. This chapter addresses the different function of directly monitoring and evaluating the quality and appropriateness of health care delivered to Medicaid enrollees.

Focused pattern of care studies contrast with random reviews of unrelated episodes or aspects of care. An example of a random review of unrelated episodes of care is: reviewing a subset or sample of the medical records of all enrollees to detect any problems in quality. Focused pattern of care studies are superior to random reviews, because they provide information about care in the aggregate as opposed to information on a limited number of cases. Information about care in the aggregate can be generalized to the care delivered at-large and thus can point the way to large scale changes in care, as opposed to addressing quality on a case by case basis (as is done in random quality reviews).

Effective focused studies should meet the following criteria:[11]

1. **Selection of Study Topics** - The clinical or health service delivery areas selected for study should reflect the distribution of health concerns within the Medicaid population and should be of significant prevalence or incidence. Additionally, study topics should meet the following criteria:

- There are objective criteria for assessing care in the clinical or health service delivery area to be monitored. These criteria should be derived from clinical practice / treatment guidelines which meet standards for practice guidelines contained in Chapter 2, "Guidelines for Internal Quality Assurance Programs of HMOs, HIOs, and PHPs Contracting With Medicaid."

- The study topic should be one in which there is likely to be opportunity to improve health status; for example, childhood immunizations.

- Study topics should not be restricted to care delivered in one type of setting: e.g., inpatient or ambulatory.

Study topics, as recommended by HCFA's Medicaid Bureau, are found in Chapter 3 and are also listed in Appendix A.

2. **Study Design** - Once the issues to be addressed through focused studies have been identified, the studies should be carefully designed if they are to produce information which is accurate, reliable, generalizable, and generally useful. To accomplish this, studies should be designed in accordance

---

[11] Criteria adapted from "Reviewer Guidelines For Evaluating Focused Studies Conducted By Plans" Draft Outline. The National Committee for Quality Assurance February 22, 1992.

with generally accepted principles of scientific research and statistical analysis. Detailed instructions for accomplishing this are found in, "Designing and Assessing Quality of Care Studies in Managed Care Settings,"[12] however, the essential steps in study design are summarized here:

a. **Framing the study question.** - It is rarely possible to evaluate every aspect of care related to a specific clinical condition or health service delivery issue. Therefore, after each study topic involving a clinical condition or health service concern has been identified, the questions each study is to answer must be refined. For example, if a plan has identified pregnancy as a clinical condition for study, there are numerous questions about quality of care that could be included in a full study, for example:

Did pregnant women receive prenatal care in accordance with certain specified clinical practice guidelines? What are the clinical practice guidelines against which care will be compared?

Does the plan have a method for identifying "high-risk" pregnancies and does it have established procedures for "high-risk" deliveries? Were these procedures appropriately used? What is the pattern of utilization of tertiary care facilities for childbirth?

What are the characteristics of pregnant enrollees who delivered low birth weight babies and how could the plan improve its service to these women?

What are the nutritional and substance abuse characteristics of enrolled pregnant women? How could the plan improve its service to pregnant women based on information obtained?

Information from enrollee satisfaction surveys, complaints, grievances, client disenrollments and State monitoring of plans may be utilized to assist in framing study questions. In addition, Medicaid recipients or advocates can also play a role in

---

[12] "Designing and Assessing Quality of Care Studies in Managed Care Settings," manual under development by the National Committee for Quality Assurance, under contract to the U.S. Department of Health and Human Services, Health Care Financing Administration, Medicaid Bureau.

determining issues to be studied as part of a particular study.

b. **Specifying practice guidelines for use in assessing care.** - When the EQRO monitors and evaluates care, it should compare the plan's performance against some concept of "good" care. What constitutes "good care" should be identified before data is obtained from plans about the health care it delivers. The Medicaid Bureau's "Guidelines for Internal Quality Assurance Programs of HMOs, HIOs and PHPs Contracting With Medicaid" call for managed care organizations themselves to monitor and evaluate the care they deliver through the use of clinical practice guidelines.

Practice guidelines, practice standards, practice advisories, or practice parameters are all terms used to refer to recommended "best practice" strategies for clinical decision making and patient care. Although the terminology may vary, all can serve as sources of quality indicators against which care delivered by the HMO/HIO can be assessed. This document uses the term "practice guidelines" although, for purposes of this document, any of these terms may be used interchangeably.

Sources of practice guidelines may be found in the American Medical Association publication, "Directory of Practice Parameters," which is published annually, or may be identified from several other sources, including government and public health publications, recommendations from medical leadership and plan providers, as well as from published practice parameters.[12]

Ideally, the practice guidelines which the HMO/HIO uses to assess care, and the guidelines used by the external review organization, should be identical. However, this may not always be the case. Regardless, the EQRO should review care in accordance with explicit guidelines approved by the State. If these guidelines are in conflict with those utilized for other purchasers of HMO/HIO services, this should be noted in the EQRO's analysis of findings and appropriately

---

[12]Examples of practice guidelines for the clinical conditions of interest may also be obtained from HCFA's Medicaid Bureau. This listing is available for informational purposes only and does not imply Medicaid Bureau endorsement of any or all of the practice guideline examples.

addressed.

c. Defining the quality indicators that will be monitored and evaluated to assess care. - From the practice guidelines, specific variables are derived to serve as indicators of the quality of care. These "quality indicators" are objective pieces of information that will be collected and analyzed to provide information to answer the study questions. For pregnancy, for example, selected quality indicators could include: birth weight, weeks of gestation at first prenatal visit, number of prenatal visits prior to delivery, or birth outcome (fetal loss or live birth).

Most quality indicators to be utilized will be "process of care" measures as opposed to outcome measures. If outcome indicators are considered, the difficulty of attributing outcomes to health care received must be addressed, as well as the problem of the infrequent occurrence of some outcomes and the resulting problem of obtaining statistically significant results.

d. Determining the methodology which the EQRO will utilize to assess care delivered - The methodology to be utilized to compare care delivered to care recommended in accordance with the identified practice guidelines should address the following:

- What will be the sources of the data to be collected? Data can be obtained from many sources: e.g., medical records, administrative data, claims data, and survey data. The EQRO will need to acknowledge and accept the diversity of data and assess each organization according to the data available from that organization until broader industry, State and national efforts to standardize data are successful. Although the sources of data may vary by plan, the EQRO should attempt to use consistent data definitions and a consistent data collection methodology to promote comparability of data across plans. Abstraction instruments should be employed by the external review entity to aid in consistency of data collection and data abstractors should be experienced in their use. This will promote internal validity and comparability across plans within a State.

- Will sampling be utilized or will all incidents which meet study question criteria be included in the study? The methodology should estimate the

prevalence of the issues under study within the plan. In plans with few Medicaid enrollees or a small universe, it may be advisable to obtain data on all Medicaid enrollees instead of sampling. Where the universe is large, the external study should sample the condition under review.

- **If sampling is to be utilized, the sample should be derived in accordance with generally accepted principles of research design and statistical analysis in order to be appropriate to the purposes and hypotheses of the study.** The sampling methodology and statistical analysis to be utilized should consider:

  - The intended uses of the data; e.g., Does the State wish to make comparisons across plans or comparisons to regional or national data? Will it be used to sanction plans? Will it be released to the public at large?

  - The nature of the data to be collected;

  - The expected prevalence of compliance / noncompliance with certain guidelines.

  - The total number of studies to be conducted by the EQRO for each particular plan. Fewer studies with larger sample sizes and more numerous studies with smaller sample sizes may pose similar administrative burdens on plans. There are trade-offs to be made between the number of studies the State desires and the sample sizes that can reasonably be pursued for each study.

  - The degree of confidence required for the data.

- **Will there be continuous monitoring or one time collection of data? - Is there a need for the** State to have certain plan performance information more frequently than annually?

- **Determining the methodology for analysis of results** - The study methodology should specify:

  - How the raw data collected from the study is to be verified.

  - the statistical analytical tests to be performed on the data.

- whether the data analysis will be able to adjust for such influences as age, severity of illness, or other variables which may affect the findings for the study questions. If no adjustments are possible, this should be discussed in the report of external review study findings.

- the performance measures to be used by the State to define "acceptable" performance by plans. For example, a State may choose to measure plan performance against national performance data, against the performance of other plans in the State, or through established "benchmarks" against which the plan will be expected to show continuous improvement.

If the State desires to utilize external quality review to make comparisons of the care given by different plans in the State, the external quality review analysis should contain descriptions of the varying sources and definitions of data collected across plans. If information is able to be collected from all plans in an identical manner and using identical definitions, plan comparisons should be more feasible. Where data collection and definitions are not identical, an explanation and discussion of the limitations on cross plan comparisons based upon the different data sources and data definitions utilized by plans should be included in the external quality review report. Until there is national or State standardization of data definitions and data collection across plans, the ability to compare information across plans will be limited.

3. Analysis and Interpretation of Study Findings - Analysis of results is not limited to the performance of statistical tests upon the raw data. "Analysis" examines data in light of other knowledge about the study population, plans, and the environment in which plans and enrollees exist. Analysis attempts to produce "information" from "data." For example, when there is variation of plans from national norms, or variation between plans, what are likely explanations? Analysis of data should be conducted with input from the plans and the State. It should produce recommendations for concrete actions which can be undertaken by plans, enrollees and the State to improve the health care received from managed care organizations.

B. Individual Case Reviews

As discussed above, population based quality of care studies are more capable of providing generalizable quality of care information than are case by case reviews of care rendered to individuals. However, on occasion, there will also be a need for review of the quality of care delivered at the level of the individual. Such individual case review is necessary for individual incidents in which:

1. the occurrence is too infrequent to make judgements about "patterns" of care, or to perform an analysis to detect "statistical" significance; or

2. the effect on an individual or individuals is so serious as to warrant individual attention.

Examples of clinical incidents which may warrant individual case review are: maternal death, childhood death (non neonatal, trauma, immunologic or oncologic related), and ambulatory surgery deaths. Individual case review may also be appropriate in instances when questions are identified about a certain type of care provided by a particular provider. States may further wish to reserve the right to refer a certain number of cases to the EQRO for individual case review on an ad-hoc basis when cases arise which do not fit into anticipated individual case review categories.

In individual case review, peer health care professionals from the EQRO should review the medical records and any other accessory information sources to determine: the anatomy of the incident; remedial action, if necessary; steps which may be taken to prevent such an occurrence in the future; and the implications of this occurrence for the managed care organizations' quality assurance program and the State's quality improvement system. This information should be included in the EQRO's report to the State on plan performance in quality of health care and health care delivery.

C. Follow-up Activities on Study and Case Review Findings

Both focused pattern of care studies and individual case review activities should result in formal written recommendations by the EQRO for actions to be undertaken by plan(s), the State Medicaid agency, or other parties (including the EQRO), as appropriate, to:

- improve the care provided by the plan to Medicaid recipients, and

- resolve detected problems.

At the end of each review cycle, the EQRO should submit to the State a written report which contains: a description of its activities, pattern of care study findings, individual case review findings, and a Follow-Up Work Plan recommending activities to be conducted and the entities which are to conduct them to resolve identified problems and improve care overall. The work plan should include measurable goals so that problem resolution and care improvement can be objectively assessed. The work plan should be jointly developed by the EQRO and the HMOs under review. **(See Section IV, Implementation, for greater discussion of this.)**

In the subsequent review cycle the EQRO should conduct verification activities to determine two things:

- Were problem resolution and quality improvement activities implemented as recommended in the Follow-Up Work Plan?

- Have Work Plan activities achieved their stated goals?

Areas in which work plan goals have been reached would require no further follow-up (although the State may wish to continue to address these areas through focused studies or case review). Areas in which problem resolution or quality improvement goals were not reached will require both ongoing quality review and further follow-up activities. The EQRO should document HMO compliance/non compliance with recommendations.

IV. IMPLEMENTATION:

There are a number of ways in which the working relationships between the State, the EQRO, and HMOs/HIOs can be structured to implement the above approach to external quality review. Each State should determine the best approach for itself based on its own resources and interests, as well as the capabilities of its EQRO. A State should also involve HMOs/HIOs in the design of the external scope of work. The external quality review activity is more likely to be a successful Quality Improvement mechanism if the HMOs under review are proactively involved in the process. Although involvement of HMOs/HIOs in the design of the external review scope of work may seem a difficult task to a State with a new or very large HMO/HIO contracting program, HCFA encourages the formation of HMO/HIO "quality groups" or other mechanisms to develop collaborative relationships for quality improvement. Some States; e.g., Minnesota, have successfully involved managed care organizations in this way.

When designing the external quality review function and

determining how it is to operate as part of the State's overall Quality Improvement System (QIS) for Medicaid Managed Care, States should construct their EQRO and HMO/HIO contracts to address each of the following:

A. Delineating the Role of the EQRO

The EQRO is the contractor to the State. At a minimum, the EQRO is fully responsible for implementing quality review activities in accordance with certain specifications determined by the State. For example, a State may require an EQRO to implement studies, case reviews and follow-up activities which may have been independently designed by the State. However, at the State's discretion, the EQRO may also have responsibilities for designing focused studies, individual case reviews, and Follow-Up Work Plans. Under this scenario, a State could elect to delegate both the design and implementation of these activities to the EQRO. Ideally, however, the design of quality review activities should be a partnership between the State and its EQRO contractor with input from managed care organizations.

The State should determine the degree of EQRO involvement in the design of external quality reviews it desires and specify this in its contract with the EQRO. The contract with the EQRO should explicitly address the following design functions and clearly state the degree and nature of EQRO responsibility for or participation in them:

1. selection of clinical conditions and/or health service delivery issues to be addressed through external quality review.

2. study design features as described in the previous section, including: refining study questions, identification of practice guidelines to be used to assess care, identification of quality indicators, and determination of study methodology.

3. analysis and interpretation of study findings.

4. determination of characteristics of cases to receive individual review.

5. structuring of Follow-Up Work Plans.

B. Length of EQRO Contract With the State

Because the external review process involves both the direct assessment of quality and the implementation and review of quality improvement activities, EQRO contracts should be of multiple years duration, unless State contracting laws

prohibit this or the State has other concerns which may necessitate contracting on a more frequent basis; e.g., the State is not satisfied with EQRO contractor performance. A multi-year contract; e.g., for three years, allows the EQRO which identified the quality issues and/or areas for improvement to actually follow-through on problem resolution and quality improvement recommendations. Follow-up is likely to be most effective when performed by the entity which investigated the care initially. However, an EQRO contract should not be for such a long period of time; e.g., five years, that the State is unable to make timely changes to the EQRO's scope of work to keep pace with changing quality assurance technology or State needs.

C. Participation of HMOs/HIOs in Designing EQRO Review Activities.

Quality improvement and problem resolution activities will be most effective if the managed care organizations participate in their design. Similar to the options that exist for including EQROs in quality review design, HMOs/HIOs may also be involved in the design of review activities. Having HMOs/HIOs participate in this way can contribute to improved quality review activities and quality of care in two ways:

1. HMO/HIO participation in quality review design will likely make implementation of the reviews easier for both the EQRO and the HMOs/HIOs, and may increase the likelihood of being able to implement the review methodology as designed;

2. Advance knowledge of the scope of an intended review of care may encourage an organization to improve care in those areas prior to the review, thus improving care sooner rather than later.

HMOs/HIOs should participate in the following quality review design activities:

1. selection of clinical conditions and/or health service delivery issues to be addressed through external quality review;

2. study design features as described in the previous section, including: refining study questions, identification of practice guidelines to be used to assess care, identification of quality indicators, and determination of study methodology;

3. analysis and interpretation of study findings;

4. determination of characteristics of cases to receive individual review; and

5. structuring of Follow-Up Work Plans.

D. Potential Variation in the Type of Clinical Conditions / Health Services Delivery Issues to Be Studied at Each Plan

In certain situations, the State may wish to vary the clinical conditions to be studied between plans. For example, a State may have different concerns for its inner city Medicaid recipients than for its rural recipients. Or, a plan which has set up an immunization tracking system satisfactory to the State may be able to produce immunization data of greater reliability than other managed care organizations. In such a situation, a State may identify immunizations to be a study topic for all HMOs/HIOs except the HMO/HIO with the immunization tracking system. The State may exempt that plan from that one particular external focused study as long as the plan provides comparable immunization data in which the State has a high degree of confidence and which shows a high degree of compliance with a State specified standard of performance.

E. Determining the Number of Focused Pattern of Care Studies to be Conducted For Each Plan

The number of studies to be conducted for each plan is, in part, a function of the methodology(ies) to be employed in conducting the quality of care studies. Complex studies need more resources than smaller studies; e.g., more data may need to be collected de novo from medical records rather than accessed from existing administrative data sets; data may need to be collected for consecutive years in order to obtain adequate sample sizes or detect trends in care; or the character of a certain condition may necessitate larger rather than smaller sample sizes.

The State has several options available to it for specifying the number of pattern of care studies to be conducted for each plan:

1. The State may require the same number of studies to be conducted by or for all plans. In this option the State has the option of requiring the EQRO to review different study issues for certain plans.

2. The State may require fewer studies from plans which have a strong history of producing information of high reliability and accuracy, and which have consistently shown compliance with agreed upon performance measures. The State would then direct the EQRO to perform or

oversee a greater number of clinical studies in plans which have poorer quality of care performance in comparison to their counterparts.

Determination of the number and complexity of studies should be made by the State in consultation with the external quality review organization and the managed care plans.

F. Methods for Implementing Focused Studies

Because of the varying capabilities of plans to provide quality of care data and to conduct pattern of care studies, any of three different approaches to utilizing the EQRO to obtain accurate pattern of care information from plans may be utilized. The variation in these approaches are intended to provide flexibility to States and plans in obtaining and providing external quality review information.

A State should choose from these approaches to direct the work of its EQRO, but is not obligated to utilize any particular one or to utilize all of them (a State should use at least one of them). A State may utilize different approaches for different HMOs/HIOs depending upon the State's knowledge about each HMO's/HIO's past performance in the provision of health care and in the implementation of quality of care studies.

Option 1. EQRO Review of an HMO/HIO Designed and Conducted Internal Study - THIS OPTION ASSUMES THE INDEPENDENT CAPABILITY OF THE MANAGED CARE ORGANIZATION TO DESIGN AND IMPLEMENT A STUDY WHICH MEETS STATE SPECIFIED PARAMETERS.

If the State has, as recommended above, informed the managed care organization of the clinical or health service delivery issues to be reviewed, study questions to be answered, quality indicators and other relevant study design features, the managed care organization may independently conduct its own study as part of its internal Quality Assurance Program (QAP). Under this option, the role of the EQRO is to review the managed care organizations' study to determine if the study methodology is valid and to perform an independent validity check of the internal study findings. If the external review organization's review supports the plan's methods and findings, then the external review organization can utilize the managed care organization's study findings in its report of plan performance to the State. If the external review organization finds that either the plan has not conducted a validly designed study which can answer the study questions, or that the study findings are not

supported by an external validity check, then the external review organization can either impose a study methodology on the plan (Option 2), below, or conduct its own study (Option 3).

At a minimum, EQRO review of an HMO's/HIO's internal study, should assess the following issues:

- Was the study question of the Plan the same as that specified by the State? If not, did the study generate the prescribed study variables defined according to the same specifications to be used for the EQRO's study?

- Was the collection of the same defined performance measures performed in a manner that preserves internal and external validity; e.g., Was the sampling methodology sound? Were reliable data collection mechanisms employed? Was it designed in accordance with generally accepted research principles?

- Does a verification subsample confirm the findings of the plan?

Based upon the EQRO's evaluation of the plan's internal study, if the plan has conducted its internal study in an acceptable manner, then the State may exempt the HMO/HIO from a full external study of this question and utilize data provided by the plan through its internal QAP.

Option 2. EQRO Design of Study With Implementation by the Managed Care Organization - IN ADDITION TO SECURING THE QUALITY OF CARE INFORMATION SOUGHT BY THE STATE, THIS APPROACH HAS A SECONDARY DESIREABLE EFFECT OF IMPROVING THE INTERNAL QUALITY ASSURANCE CAPABILITY OF THE PLAN.

A managed care organization may not have sufficient resources or expertise to independently and competently design a focused pattern of care study which meets the criteria determined by the State. In such a situation, if the HMO/HIO is willing to implement a quality assurance study in accordance with study design specifications established by the EQRO and the State, the EQRO may provide the HMO/HIO with study design specifications to enable the HMO/HIO to conduct its own internal study to meet State specifications. In this option, the EQRO and the HMO/HIO would work collaboratively to design a study for the plan which would meet study specifications established by the EQRO

and State for the external quality reviews. The managed care organization is then responsible for implementing the study in accordance with these specifications. At the conclusion of the implementation of the study, the EQRO would perform the same evaluation of the plan's focused pattern of care study as it does for studies independently designed and conducted by HMOs as in option #1, above. If the study meets all requirements, the EQRO may utilize this data in its plan performance report to the State.

If the plan is not willing to accept such guidance, or if the plan's study fails to meet criteria for acceptable performance, then the EQRO will both design and implement quality of care studies as in option 3, below.

Option 3. Design and Implementation of Focused Studies Solely by the EQRO.

If the State determines, with input from the EQRO, that a review of the plan's internal studies is not feasible, or that an effort at having a managed care organization implement a study in accordance with State/EQRO specifications is not likely to be successful, the EQRO shall implement quality of care studies to answer the State's areas of concern in accordance with the conceptual model discussed in Part III above. In this option, the role of the HMO shall be to provide or allow access to clinical or health services data required by the EQRO. This data may be in the form of medical records or data from administrative or other data sets. If information is obtained from sources other than medical records, the EQRO shall also perform a verification of the accuracy of the data base.

G. Individual Case Review

Since focused pattern of care studies generate information of greatest utility for quality improvement, and case by case review consumes more resources on a per case basis, individual case review should be reserved for unique clinical care situations which meet either of the two criteria described in Part III:

1. the occurrence is too infrequent to make judgements about "patterns" of care or perform analyses to detect "statistical" significance; or

2. the effect on an individual or individuals is so serious as to warrant individual attention.

The State is responsible for identifying the criteria for selecting cases which will receive individual quality review. Because individual case review should be undertaken in very few cases, it is appropriate that it be well targeted. As with the process for external review overall, the effectiveness of targeting cases for individual case review process is likely to be most effective if designed jointly by the EQRO and the State, with input from the HMOs/HIOs.

EQRO statisticians may be helpful in identifying clinical conditions or events which happen so rarely that pattern of care studies are not feasible. HMOs/HIOs may be helpful in identifying clinical or health services delivery incidents which warrant individual attention. The State may also utilize information from grievances and State monitoring of plans to identify incidents which require individual case review. The State may also find it helpful to look to its Fee-For-Service program to identify examples of cases appropriate for individual review.

Cases for individual review may not always be defined by clinical criteria. For example, a State may direct that certain health service delivery events always be reviewed; e.g., all complaints of denial of emergency care. In addition, it may not be possible to anticipate in the contract with the EQRO all cases which should receive individual review in the course of a given time period; e.g., 12 months. Because of this, the State may wish to cite in its contract with the EQRO the following category for individual case review: "individual cases referred to the EQRO for case review at the State's discretion."

H. Follow-Up Activities

After the EQRO has completed its focused studies and individual case reviews for each plan, it will produce a set of preliminary findings and recommendations for: problem resolution, quality improvement, and follow-up activities. These should be reviewed and commented upon jointly by plans and the State before being finalized. The State has the discretion to determine how and when this review is to take place. The following options are examples of varying degrees of State involvement in this process. As these examples represents points along a continuum of State involvement, States may decide to be involved consistent with one of these examples or in other intermediate ways.

Example 1: High Level of State Involvement - A State could require the EQRO to submit its preliminary

findings to the State directly. The State would then take total responsibility for reviewing the findings with managed care plans and developing a final report and follow-up work plan to be implemented by the EQRO.

Example 2: Low Level of State Involvement - A State could direct the EQRO to meet with each plan it reviewed to present its findings to the plan and develop a mutually agreed upon problem resolution, quality improvement, and follow-up work plan. The EQRO would then submit a final report to the State.

Example 3: Midlevel State Involvement - The State may direct the EQRO to implement a process for HMO review and comment prior to finalizing the EQRO's annual report to the State. The process could be jointly developed and implemented by the State and the EQRO.

It is necessary to have the review of preliminary findings by the plans in order to assist in:

- the interpretation of the quantitative findings of the EQRO, and
- the development of follow-up plans for problem resolution and quality improvement.

For example, if one plan has a significantly lower rate of childhood immunizations than other plans in the same area, what practices employed by the other plans could be adopted by the plan with lower immunization rates? Practices successfully employed by other plans and their success rates are useful in developing problem resolution/quality improvement plans with reasonable goals. Further, if a plan's practice guidelines differ from those used by the EQRO in assessing care, this will be noted by the plan and should accompany the annual quality report to aid in analyzing differences in plan performance.

Regardless of the degree of involvement of the State in finalizing the preliminary findings of the EQRO, all States should be highly involved in the follow-up of the final findings of the annual EQRO quality review. States should follow each managed care organizations' progress in meeting quality improvement goals and in correcting any problems identified by the EQRO on an annual basis, or more frequently as necessary. Even if a State delegates follow-up activities to its EQRO contractor, the State cannot delegate its responsibility for being aware of: the quality of care provided by its managed care contractors; any necessary follow-up activities to be taken by the EQRO; or

the status of the EQRO's implementation of follow-up activities. Because the State is responsible for follow-up on documented quality of care problems, it is recommended that the EQRO submit status reports every four to six months to the State on its follow-up activities on the preceding year's findings. Finally, in instances where a managed care organization's quality of care has shown significant deficiencies, States should consider the appropriateness and applicability of intermediate sanctions.

V. CONFIDENTIALITY AND DISCLOSURE OF INFORMATION

States should make clear to both the EQRO and managed care organizations how the State will utilize information obtained from the reviews in any planned release of data, report of quality review findings, or requests for information from other public or private entities. The State should delineate what, if any, authority the EQRO has to release any plan specific or aggregate data other than information specific to a managed care organization to that same organization. If the State Medicaid agency contracts with a Utilization and Quality Control Peer Review Organization (PRO) to conduct external quality reviews, disclosure of external review information is governed by Section 1160 of the Social Security Act, "Protection Against Disclosure of Information." If a State uses an entity other than a PRO, disclosure of information is governed by State law and the confidentiality and data requirements of the Medicaid program.

VI. SPECIFICATIONS FOR EXTERNAL QUALITY REVIEW ORGANIZATIONS

The external quality review process is based in scientific principles governing research design and statistical analysis. In addition, the focus of the reviews is on health care services and their delivery. Because of this, the organization which conducts the reviews should have personnel who are educated and experienced in the conduct of health services research and the provision of medical services. Further, the EQRO should provide these individuals with appropriate supervision in the conduct of their work. Optimally, States should select external review organizations that employ reviewers with expertise in prepaid organized health care delivery systems and their internal quality assurance mechanisms. However, at a minimum, EQROs should have personnel with the following competencies:

A. Clinical Expertise.

The EQRO may utilize staff level personnel with varying

clinical experience; e.g., medical, nursing, dental or other allied health professions. However, because the EQRO will be making measurements and assessments of the delivery of medical and related health services, clinical assessment activities undertaken by the EQRO should be under the supervision of an individual with the appropriate education and experience in:

1. assessing broad based medical and other health care services, through the use of quality assurance technology such as: practice guidelines, quality indicators, and performance measures.

2. utilizing practice guidelines - their development, evaluation and implementation.

3. designing, implementing and assessing the effectiveness of corrective action plans / quality improvement activities.

4. (to the extent possible) reviewing HMOs and HIOs.

In addition, the EQRO should demonstrate that it has access to medical and health care experts in specific health care areas; e.g. specialty care, on an ad-hoc basis.

B. Health Services Research Expertise.

Because the primary activities to be undertaken by EQROs are designing, assessing and implementing focused quality of care studies, the EQRO should have sufficient expertise in research methodology and statistical analytical methods to know how to undertake these activities and to instruct managed care organizations, as necessary, where a managed care organization itself wishes to undertake studies. EQROs should have sufficient personnel resources in research and statistical analytical methods in order to provide assistance to managed care organizations and assess the soundness of focused quality of care studies on a timely basis.

APPENDICES

CLINICAL AND HEALTH SERVICES DELIVERY AREAS OF CONCERN

Clinical Areas of Concern:

1. Childhood Immunizations (Required)
2. Pregnancy (Required)
3. Breast Cancer/ Mammography
4. Cervical Cancer/ Pap Smears
5. Lead toxicity
6. Comprehensive Well Child Periodic Health Assessment
7. HIV status
8. Asthma
9. Hysterectomies
10. Diabetes
11. ETOH and Other Substance Abuse
12. Hypertension
13. Sexually Transmitted Diseases
14. Heritable Diseases (newborn screens)
15. Coronary Artery Disease
16. Motor Vehicle Accidents
17. Pregnancy prevention
18. Tuberculosis
19. Sickle Cell Anemia
20. Failure to thrive
21. Hepatitis B
22. Otitis Media
23. Mental health

24. Prescription Drug Abuse

25. Hip Fractures

26. Cholesterol Screening and Management

27. Treatment of Myocardial Infarctions

28. Prevention of Influenza

29. Smoking Prevention and Cessation

30. Medical Problems of the Frail Elderly;e.g., incontinence and confusion

31. Hearing and Vision Screening and Services for Individuals Less Than 21 Years of Age

32. Dental Screening and Services for Individuals Less Than 21 Years of Age

33. Domestic Violence

Health Services Delivery Areas of Concern:

1. access to care
2. utilization of services
3. coordination of care
4. continuity of care
5. health education
6. emergency services

MATHEMATICA
Policy Research, Inc.

600 Maryland Ave. S.W., Suite 550
Washington, DC 20024-2512
TEL (202) 484-9220
FAX (202) 863-1763

EVALUATION OF THE MEDICAID MANAGED CARE QUALITY ASSURANCE REFORM INITIATIVE (QARI) STATE DEMONSTRATIONS

SUMMARY

Under a grant from the Henry J. Kaiser Family Foundation, Mathematica Policy Research, Inc. (MPR) will evaluate the Medicaid Managed Care Quality Assurance Reform Initiative State Demonstrations. The demonstrations are being cosponsored by the Foundation and the Health Care Financing Administration (HCFA). The National Academy for State Health Policy will manage the demonstrations on behalf of the funders. Marsha Gold, Sc.D., is the MPR Project Director for the Evaluation.

The evaluation will include a comprehensive assessment of the feasibility and technical requirements of the system, including recommendations for system improvement. It also will examine the ability of the system to identify and correct problems and to enhance quality of care. The evaluation will emphasize timely reporting of results and recommendations with a focus on brief papers that can inform the policy debate and provide early feedback on any desirable refinements.

THE MEDICAID MANAGED CARE QUALITY ASSURANCE REFORM INITIATIVE STATE DEMONSTRATIONS

In 1990, HCFA began the Quality Assurance Reform Initiative (QARI) to design a more effective approach to monitoring and improving the quality of health care delivered in managed care programs used by Medicaid recipients. The effort built on substantial advances made in the field of quality assurance and sought to apply those lessons to Medicaid managed care delivery systems.

QARI creates both a framework and specific guidelines for the state Medicaid agency, the participating plans, and an independent review entity in monitoring quality. It was developed by HCFA with input from state officials, managed care plans, congressional staff, and consumer advocates. Based on a competitive request-for-proposals, three states--Ohio, Minnesota, and Washington--were awarded grants from the Foundation to test the feasibility and effectiveness of QARI. States will receive funding for two years to support implementation and operation of QARI, with the expectation that this will create a firm basis to make QARI an integral part of state Medicaid managed care program oversight.

The objectives of the demonstrations are:

- To test the QARI system for Medicaid managed care quality assurance and to determine its effectiveness in monitoring quality of care.
- To increase state capacity to implement and manage Medicaid managed care quality assurance reforms.

- To provide HCFA with information to refine the quality assurance guidelines based on the experience of the demonstration states; and

- To provide Congress and others with information on whether QARI can be relied upon to protect the quality of care provided to Medicaid recipients in managed care.

OVERVIEW OF THE EVALUATION

MPR will evaluate the first three years' operational experience of the three states participating in the QARI demonstration. The evaluation will have two major components.

The first component will involve a comprehensive assessment of the implementation and operation of the QARI system, and will produce recommendations for improvement. MPR will examine issues relevant to all parties involved in the QARI system. The evaluation will include in-depth interviews and collection of information from state officials, managed care plans, external review organizations, and consumers. Annual visits will be made to each of the three demonstration states, with additional information obtained through periodic telephone and other contacts.

The second component will involve an analysis, to the extent feasible, of system impact. This will include an assessment of how well the system works to identify and correct problems and a comparative analysis of the quality of care provided in Medicaid managed care settings with QARI as compared with Medicaid managed care without QARI and with fee-for-service Medicaid. The analysis will be based on information obtained in site visits and available data on managed care and fee-for-service Medicaid.

Early reporting of results is an important feature of the evaluation. It is anticipated that early feedback on issues of implementation and technical feasibility will be available by the end of the first year. Subsequent reports and papers will present more in-depth or longer-term findings. Results will be disseminated broadly, and will emphasize recommendations to improve both the content and implementation of QARI.

STANDARDS for the ACCREDITATION of Managed Care Organizations

1993 Edition

ISBN: 0-9635158-0-2

FOREWORD

To develop standards that effectively evaluate the structure and function of medical and quality management systems in managed care organizations, the National Committee for Quality Assurance (NCQA) worked with the managed care industry, health care purchasers, state regulators, and consumers in an extensive review and development process. The result of this process is an important consensus, forged between managed care organizations and their customers. The Standards validate that a managed care organization is founded on principles of quality and is continuously improving the clinical care and services provided.

The *Standards for Accreditation of Managed Care Organizations* are used by NCQA reviewers to evaluate a managed care organization in the following areas:

- quality improvement,
- utilization management,
- credentialing,
- members' rights and responsibilities,
- preventive care services guidelines, and
- medical records.

This edition of the *Manual* contains the first revisions of the Standards, which were originally promulgated in 1991. The revised standards were approved by the NCQA Board of Directors in June 1992. They will be implemented for accreditation decision purposes in January 1993. We anticipate the *Manual* will be revised on an annual basis.

Many of the revisions were editorial, to assist NCQA staff in applying the Standards consistently. However, two changes were broad in scope and affect several of the Standards. They include the following:

Delegated Activities. Both the 1991 Standards and those in this edition of the *Manual* address delegated and non-delegated activities, but take a somewhat different approach. Under the 1991 Standards, there were certain specific Standards that addressed delegated activities, and all other Standards addressed non-delegated activities. In the revised Standards, published in this edition of the *Manual*, both delegated and non-delegated activities will be considered when assessing compliance with each Standard.

Standards Designated for Monitoring Status. The 1991 Standards included several that were designated for monitoring status, which meant that compliance with these particular Standards was not considered in accreditation decisions for surveys performed in 1992. Effective with this edition of the *Manual*, the designation has been eliminated, and accreditation surveys conducted in 1993 will consider Standards previously designated for monitoring status.

Credentialing. The revised Standards for Credentialing make more explicit the requirement that credentialing be ongoing and up-to-date. They also require that a plan conduct an initial visit to the offices of primary care providers, obstetricians/gynecologists, and other high-volume specialists.

Recredentialing. The revised Standards for Recredentialing also make more explicit the requirement that recredentialing be ongoing and up-to-date. In addition, the specific information now required in the recredentialing process is delineated, including: primary verification of documents, provider attestation statements, updated information from recognized monitoring organizations, and on-site visits to all primary care providers, obstetricians/gynecologists, and other high-volume specialists.

The NCQA review process examines the organization's quality improvement program structure, tests quality improvement processes, and looks for evidence that quality improvement activities have resulted in measurable improvement in the plan's performance, in both clinical and service areas. A similar assessment and analysis is completed for the plan's utilization management, preventive health services, credentialing, and member rights and responsibilities programs. In addition, members of the assessment team review a sample of medical records as an independent assessment of the quality of medical record documentation and the quality of care provided by plan physicians.

A rating scale is used to assess the managed care organization's level of compliance with NCQA Standards. The scale contains the five compliance designations that follow:

- Full Compliance: The plan consistently meets all provisions of the Standard.
- Significant Compliance: The plan meets most provisions of the Standard.
- Partial Compliance: The plan meets some provisions of the Standard.
- Minimal Compliance: The plan meets few provisions of the Standard.
- Non-compliance: The plan fails to meet provisions of the Standard.
- Not applicable (N/A): The Standard does not apply to the plan.

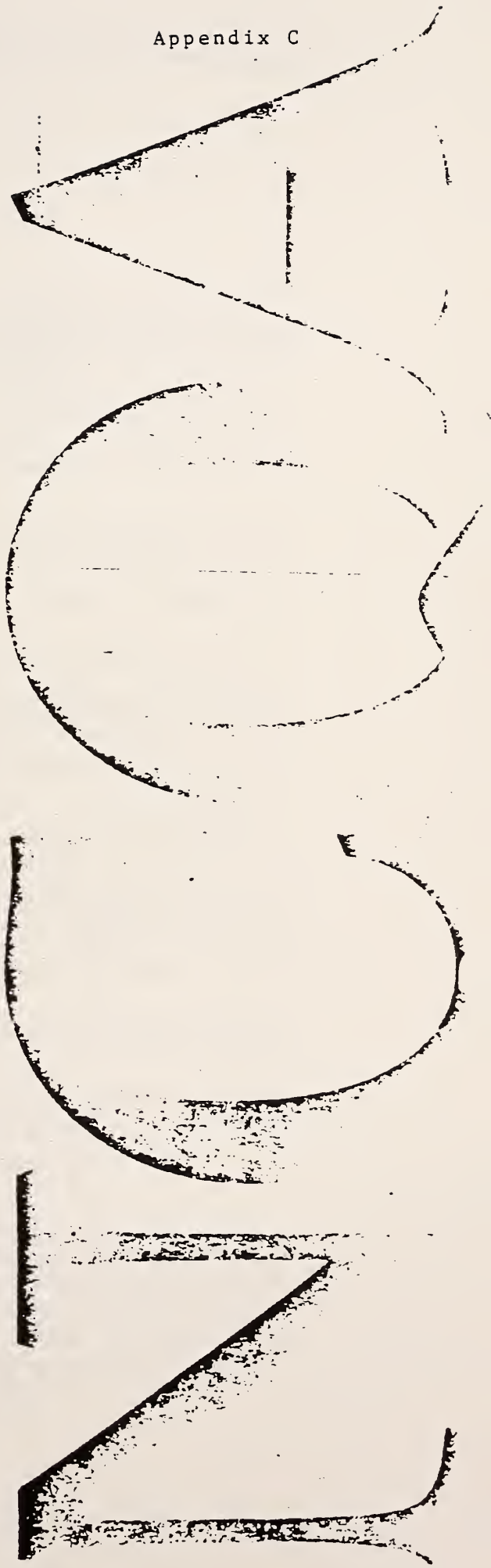
NCQA is committed to working with managed care organizations to ensure that the accreditation review process is a positive and useful experience. We encourage those who use this *Manual* to forward any suggestions, for we are committed to continuously improving our Standards and review process. Our goal is to increase the value of NCQA accreditation to organizations seeking accreditation, and to the audiences who seek help in assessing the quality of those organizations.

Margaret E. O'Kane

President

CONTENTS

STANDARDS FOR ACCREDITATION



QUALITY IMPROVEMENT

QI 1.0 PROGRAM STRUCTURE

Organizational arrangements and responsibilities for quality improvement (QI) processes are clearly defined and assigned to appropriate individuals. (Reviewers will consider delegated as well as non-delegated activity.)

QI 1.1 There is a written description of the QI program that outlines program structure and design.

QI 1.2 The program description is reviewed annually and updated as necessary.

QI 1.3 There is a designated senior executive who is responsible for program implementation.

QI 1.4 The managed care organization's medical director has substantial involvement in QI activities.

QI 1.5 There is a committee that oversees and is involved in QI activities.

QI 1.6 The role, structure and function, including frequency of meetings, of the QI committee are specified in the program description.

QI 1.7 The managed care organization's providers participate actively in the QI committee.

QI 1.8 Resources dedicated to the program are adequate to meet needs (eg, personnel, analytic capabilities, data resources).

QI 1.9 There are contemporaneous (ie, created at the time the activity is being conducted) records reflecting actions of the committee.

QI 1.10 There is an annual QI work plan, or schedule of activities, that includes the following:

QI 1.10.1 Objectives, scope, and planned projects or activities for the year;

QI 1.10.2 Planned monitoring of previously identified issues, including tracking of issues over time; and

QI 1.10.3 Planned evaluation of the QI program.

QI 2.0 ACCOUNTABILITY TO THE GOVERNING BODY

The QI committee is accountable to the governing body of the managed care organization. The governing body should be the board of directors, or a committee of senior management may be designated in instances in which the board's participation with QI issues is not direct. There is evidence of a formally designated structure, accountability at the highest levels of the organization, and ongoing and/or continuous oversight of the QI program.

QI 2.1 The governing body has formally designated a committee to provide oversight of QI, or formally decides to provide such oversight as a committee of the whole.

QI 2.2 There is documentation that the governing body has approved the overall QI program.

QI 2.3 There is documentation that the governing body has approved an annual QI plan.

QI 2.4 The governing body, or designated committee, receives regular written reports from the QI program delineating actions taken and improvements made. The governing body takes action when appropriate.

QI 2.5 The governing body reviews a written annual report on the QI program. (See QI 10.1)

QI 3.0 COORDINATION WITH OTHER MANAGEMENT ACTIVITY

Findings, conclusions, recommendations, actions taken, and results of actions taken are documented and reported to appropriate individuals within the managed care organization and through established QI channels. (Reviewers will consider delegated as well as non-delegated activity).

QI 3.1 QI information is used in recredentialing, recontracting, and/or annual performance evaluations.

QI 3.2 QI activities are coordinated with other performance monitoring activities, including utilization management, risk management, and resolution and monitoring of member complaints and grievances.

QI 3.3 There is a linkage between QI and other management functions of the managed care organization. Examples of such linkages include network changes, benefits redesign, medical management systems, practice feedback to providers, and patient education.

QI 4.0 PROVIDER CONTRACTS

Requirements to participate in QI activities are incorporated in all provider contracts and employment agreements. Contracts specify that hospitals, physicians, and other contractors will allow the managed care organization access to the medical records of their members.

QI 5.0 SCOPE AND CONTENT

There is an ongoing QI program designed to objectively and systematically monitor and evaluate the quality and appropriateness of care and service provided members, and to pursue opportunities for improvement. The scope and content of the program reflect the delivery system of the managed care organization. (Reviewers will consider delegated as well as non-delegated activity).

QI 5.1 The scope of the QI program is comprehensive and includes both the quality of clinical care and the quality of service.

QI 5.2 Members may offer suggestions for QI.

QI 5.3 Monitoring and evaluation of clinical issues reflects the population served by the managed care organization, in terms of age groups, disease categories, and special risk status.

QI 5.4 Monitoring and evaluation of clinical issues includes:

QI 5.4.1 Services provided in institutional settings;

QI 5.4.2 Services provided in noninstitutional settings, including, but not limited to, practitioner offices and home care; and

QI 5.4.3 Primary care and major specialty services, including mental health.

QI 6.0 IMPORTANT ASPECTS OF CARE AND SERVICE

The QI process uses a variety of mechanisms to identify important areas for improvement and to establish meaningful priorities. (Reviewers will consider delegated as well as non-delegated activity).

QI 6.1 The monitoring and evaluation of important aspects of care and service includes high-volume, high-risk services.

QI 6.2 The managed care organization is accountable for adopting and using practice guidelines or explicit criteria that are based on reasonable medical evidence and reviewed by managed care organization providers.

QI 6.2.1 There is a process for updating the guidelines periodically.

QI 6.2.2 A mechanism for communicating the guidelines to managed care organization providers has been implemented.

QI 6.2.3 Performance is assessed against the guidelines.

QI 6.3 The managed care organization evaluates the continuity and coordination of care members received.

QI 6.4 The managed care organization has mechanisms to detect underutilization and overutilization.

QI 6.5 The managed care organization has established standards for access (eg. to routine, urgent, and emergency care; telephone appointments; advice; and member service lines). Performance on these dimensions of access is assessed against these standards.

QI 7.0 MEASUREMENT AND IMPROVEMENT

The managed care organization uses measurements and QI data collection and analysis to track quality improvement. (Reviewers will consider delegated as well as non-delegated activity).

QI 7.1 Quality indicators that are objective, measurable, and based on current knowledge and clinical experience are used to monitor and evaluate each important aspect of care and service identified.

QI 7.1.1 The managed care organization has performance goals and/or a benchmarking process for each indicator.

QI 7.2 Appropriate methods and frequency of data collection are used for each indicator.

QI 7.2.1 QI activities include the collection of necessary data.

QI 7.3 Data collected through monitoring and evaluation activities are analyzed.

QI 7.3.1 Appropriate clinicians evaluate data on clinical performance of practitioners.

QI 7.3.2 Multidisciplinary teams are used, where indicated, to analyze and address systems issues.

QI 8.0 ACTION AND FOLLOW-UP

The managed care organization takes actions to improve quality and assesses the effectiveness of actions through systematic follow-up. (Reviewers will consider delegated as well as non-delegated activity).

QI 8.1 There is evidence that results of evaluation are used to improve clinical care and service.

QI 8.2 There is a systematic method of tracking areas identified for improvement to assure that appropriate action is taken.

QI 8.3 The managed care organization assures follow-up of identified issues to determine whether actions have been effective.

QI 9.0 EFFECTIVENESS OF THE QI PROGRAM

The managed care organization evaluates the overall effectiveness of the QI program. (Reviewers will consider delegated as well as non-delegated activity).

QI 9.1 There is an annual written report on quality, which includes a report of completed QI activities, trending of clinical and service indicators and other performance data, and demonstrated improvements in quality.

QI 9.2 There is evidence that QI activities have contributed to improvement in the care and services provided members.

QI 10.0 DELEGATION OF QI ACTIVITY

If the managed care organization delegates any QI activities to contractors, there is evidence of oversight of the contracted activity.

QI 10.1 There is a written description of

QI 10.1.1 delegated activities;

QI 10.1.2 the delegate's accountability for these activities;

QI 10.1.3 the frequency of reporting to the managed care organization; and

QI 10.1.4 the process by which delegation will be evaluated.

QI 10.2 There is evidence of

QI 10.2.1 approval of the delegate's QI program; and

QI 10.2.2 evaluation of the regular specified reports.

UTILIZATION MANAGEMENT

UM 1.0 The managed care organization has a documented utilization management (UM) program description that describes both delegated and non-delegated activities.

- **UM 1.1** The UM program description includes, at a minimum, policies and procedures to evaluate medical necessity, criteria used, information sources, and the process used to review and approve the provision of medical services.
- **UM 1.2** There is a mechanism for updating the UM program description on a periodic basis, which is specified by the managed care organization.

Note: Standards 2.0 through 6.0 are applicable to managed care organizations with preauthorization and concurrent review programs. (Reviewers will consider delegated as well as non-delegated activity).

UM 2.0 Where procedures are used for preauthorization and concurrent review, qualified medical professionals supervise review decisions.

- **UM 2.1** A physician conducts a medical appropriateness review on any denial; and
- **UM 2.2** The managed care organization uses, as needed, physician consultants from appropriate specialty areas of medicine and surgery who are certified by the applicable American Board of Medical Specialties.

UM 3.0 There is a set of written utilization review decision protocols that is based on reasonable medical evidence.

- **UM 3.1** Criteria for appropriateness of medical services are clearly documented and available, upon request, to participating physicians.
- **UM 3.2** There is a mechanism for ascertaining the consistency of application of criteria across reviewers.
- **UM 3.3** There is a mechanism for updating review criteria periodically.
  - **UM 3.3.1** The timing of the update is specified by the managed care organization.

UM 4.0 Efforts are made to obtain all necessary information, including pertinent clinical information and consultation with the treating physician, as appropriate.

UM 5.0 Decisions are made in a timely manner, depending on the urgency of the situation.

UM 6.0 Reasons for denial are clearly documented and available to the member. Notification of a denial includes appeal process information.

UM 7.0 There are mechanisms to evaluate the effects of the program, using member satisfaction data, provider satisfaction data, and/or other appropriate means.

UM 8.0 If the managed care organization delegates any UM activities to contractors, there is evidence of oversight of the contracted activity.

- **UM 8.1** There is a written description of
  - **UM 8.1.1** delegated activities;
  - **UM 8.1.2** the delegate's accountability for these activities;
  - **UM 8.1.3** the frequency of reporting to the managed care organization; and
  - **UM 8.1.4** the process by which delegation will be evaluated.
- **UM 8.2** There is evidence of
  - **UM 8.2.1** approval of the delegate's UM program; and
  - **UM 8.2.2** evaluation of the regular, specified reports.

CREDENTIALING

CR 1.0 The managed care organization has written policies and procedures for the credentialing process that include the original credentialing, recredentialing, recertification, and/or reappointment of physicians and other licensed independent practitioners who fall under its scope of authority and action.

CR 2.0 The governing body, or the group or individual to whom the governing body has formally delegated the credentialing function, reviews and approves credentialing policies and procedures.

CR 3.0 The managed care organization designates a credentialing committee or other peer review body that makes recommendations regarding credentialing decisions.

CR 4.0 The managed care organization identifies those practitioners who fall under its scope of authority and action.

CR 4.1 Included, at a minimum, are all physicians and other licensed independent practitioners listed in the managed care organization's literature for members.

Note: Standards 5.0 through 8.0 apply to the initial credentialing process. Reviewers will consider both delegated and non-delegated activity. Reviewers will also consider whether credentialing activities are ongoing and up-to-date.

CR 5.0 The initial credentialing process is ongoing and up-to-date. At a minimum, the program obtains and reviews verification of the following from primary sources:

CR 5.1 A current valid license to practice;

CR 5.2 Clinical privileges in good standing at the hospital designated by the practitioner as the primary admitting facility;

CR 5.3 A valid DEA or CDS certificate, as applicable (viewing the actual certificate will constitute primary verification);

CR 5.4 Graduation from medical school and completion of a residency, or Board certification, as applicable;

CR 5.5 Work history;

CR 5.6 Current, adequate malpractice insurance according to the managed care organization's policy; and

CR 5.7 Professional liability claims history.

CR 6.0 The applicant completes an application for membership.

CR 6.1 The application includes a statement by the applicant regarding

CR 6.1.1 physical and mental health status;

CR 6.1.2 lack of impairment due to chemical dependency/substance abuse;

CR 6.1.3 history of loss of license and/or felony convictions; and

CR 6.1.4 history of loss or limitation of privileges or disciplinary activity.

CR 6.2 There is an attestation by the applicant to the correctness/completeness of the application.

CR 7.0 There is evidence that the managed care organization requests information on the practitioner from recognized monitoring organizations.

CR 7.1 The managed care organization has requested information from the National Practitioner Data Bank.

CR 7.2 The managed care organization has requested information from the State Board of Medical Examiners, or the Department of Professional Regulations (if available).

CR 7.3 The managed care organization has reviewed for previous sanction activity by Medicare and Medicaid.

CR 8.0 There is an initial visit to each potential primary care practitioner's office and to the offices of obstetricians/gynecologists and other high-volume specialists.

CR 8.1 The visit results in documentation of a structured review of the site and of medical recordkeeping practices, to ensure conformance with the managed care organization's standards.

Note: Standards 9.0 through 12.0 apply to the recredentialing or recertification process.

CR 9.0 There is a process for the periodic verification of credentials (recredentialing, reappointment, or recertification) that is ongoing and up-to-date.

CR 9.1 There is evidence that the process is implemented at least every two years.

CR 9.2 At a minimum, the recredentialing, recertification, or reappointment process includes verification from primary sources of

CR 9.2.1 a valid state license to practice;

CR 9.2.2 clinical privileges in good standing at the hospital designated by the practitioner as the primary admitting facility;

CR 9.2.3 a valid DEA or CDS certificate, as applicable (viewing the actual certificate will constitute primary verification;

CR 9.2.4 board certification, as applicable;

CR 9.2.5 current, adequate malpractice insurance, according to the managed care organization's policy; and

CR 9.2.6 professional liability claims history.

CR 9.3 The recredentialing process includes a current statement by the applicant regarding

CR 9.3.1 physical and mental health status; and

CR 9.3.2 lack of impairment due to chemical dependency/substance abuse.

CR 10.0 There is evidence that the managed care organization requests information from recognized monitoring organizations.

CR 10.1 The managed care organization has requested information from the National Practitioner Data Bank.

CR 10.2 The managed care organization has requested information from the State Board of Medical Examiners, or the Department of Professional Regulations (if available).

CR 10.3 The managed care organization has reviewed for previous sanction activity by Medicare and Medicaid.

CR 11.0 The recredentialing, recertification or performance appraisal process includes review of data from

CR 11.1 member complaints;

CR 11.2 results of quality reviews;

CR 11.3 utilization management; and

CR 11.4 member satisfaction surveys.

CR 12.0 The recredentialing process includes an on-site visit to provider offices.

CR 12.1 The visit results in documentation of a structured review of the site and of medical recordkeeping practices, to ensure conformance with the managed care organization's standards.

CR 12.2 The following offices should be visited:

CR 12.2.1 all primary care providers;

CR 12.2.2 all obstetricians/gynecologists; and

CR 12.2.3 high volume specialists.

CR 13.0 The managed care organization has policies and procedures for reducing, suspending, or terminating practitioner privileges.

CR 13.1 There is a mechanism for, and evidence of implementation of reporting to appropriate authorities serious quality deficiencies resulting in suspension or termination.

CR 13.2 There is an appeal process for instances in which the managed care organization chooses to reduce, suspend, or terminate a practitioner's privileges. The managed care organization affirmatively makes known to the practitioner the procedure by which to appeal an adverse determination.

CR 14.0 If the managed care organization delegates credentialing (and recredentialing, recertification, or reappointment) activities, the following safeguards exist:

CR 14.1 There is a written description of the delegated activities, and the delegate's accountability for these activities.

CR 14.2 The managed care organization retains the right to approve new providers and sites, and to terminate or suspend individual providers.

CR 14.3 The managed care organization monitors the effectiveness of the delegate's credentialing and reappointment or recertification processes at least annually.

MEMBERS' RIGHTS AND RESPONSIBILITIES

RR 1.0 The managed care organization demonstrates a commitment to treating members in a manner that respects their rights.

RR 1.1 At a minimum, the managed care organization has a written policy that recognizes the following rights of members to

RR 1.1.1 voice grievances about the managed care organization or care provided;

RR 1.1.2 be provided with information about the managed care organization, its services, the practitioners providing care, and members' rights and responsibilities;

RR 1.1.3 participate in decision-making regarding their health care; and

RR 1.1.4 be treated with respect and recognition of their dignity and need for privacy.

RR 2.0 The managed care organization has a written policy that addresses members responsibility for cooperating with those providing health care services.

RR 2.1 The written policy addresses the members' responsibility for

RR 2.1.1 providing, to the extent possible, information professional staff need in order to care for the member; and

RR 2.1.2 following instructions and guidelines given by those providing health care services.

RR 3.0 The managed care organization provides a copy of policies on members' rights and responsibilities to all participating providers and directly to members.

RR 4.0 The managed care organization has a timely and organized system(s) for resolving members' complaints and formal grievances. (Reviewers will consider delegated as well as non-delegated activity).

RR 4.1 The system(s) includes:

RR 4.1.1 Procedures for registering and responding to complaints and grievances in a timely fashion;

RR 4.1.1.1 The managed care organization establishes and monitors standards for timeliness.

RR 4.1.2 Documentation of the substance of complaints, grievances and actions taken;

RR 4.1.3 Procedures to ensure a resolution of the complaint or grievance;

RR 4.1.4 Aggregation and analysis of complaint and grievance data and use of the data for QI; and

RR 4.1.5 An appeal process for grievances that includes at least the following:

RR 4.1.5.1 The member has a right to a review by a grievance panel;

RR 4.1.5.2 The member has a right to a second review with different individuals;

RR 4.1.5.3 At least one of the levels of review permits the member to appear before the panel; and

RR 4.1.5.4 There is an expedited procedure for emergency cases.

RR 5.0 The managed care organization informs members about services provided, access to services, charges, and scheduling.

RR 5.1 Members are provided a written statement that includes information on the following:

RR 5.1.1 The managed care organization's policy on referrals for specialty care;

RR 5.1.2 Provisions for after-hours and emergency coverage;

RR 5.1.3 Benefits and services included and excluded from membership and how to obtain them. This includes a description of

RR 5.1.3.1 any special benefit provisions (eg, copayment, higher deductibles, rejection of claim) that may apply to service obtained outside the system, and

RR 5.1.3.2 the procedures for obtaining out-of-area coverage;

RR 5.1.4 Charges to members, if applicable, including

RR 5.1.4.1 policy on payment of charges, and

RR 5.1.4.2 copayments and fees for which the member is responsible;

RR 5.1.5 Procedures for notifying those members affected by

RR 5.1.5.1 termination or change in any benefits,

RR 5.1.5.2 termination of any services, or

RR 5.1.5.3 termination of any service delivery office/site;

RR 5.1.6 Procedures for appealing decisions adversely affecting the member's coverage, benefits, or relationship to the managed care organization;

RR 5.1.7 Procedures for changing practitioners;

RR 5.1.8 Procedures for disenrollment of nongroup subscribers; and

RR 5.1.9 Procedures for voicing complaints and/or grievances, and for recommending changes in policies and services.

RR 5.2 The managed care organization takes steps to ensure that services offered are accessible to members.

RR 5.2.1 The points of access to primary care, specialty care, and hospital services are identified for members.

RR 5.2.2 Members are informed about how to obtain the names, qualifications, and titles of the professionals providing and/or responsible for their care.

RR 6.0 Member information is comprehensible and well designed.

RR 6.1 Member information is written in language that is readable, easily understood, and consumer-tested, if possible.

RR 6.2 Member information is available, as needed, in the language(s) of the major population groups served.

RR 7.0 The managed care organization acts to ensure that confidentiality of specified patient information and records is protected.

RR 7.1 The managed care organization has written confidentiality policies and procedures.

RR 7.2 The managed care organization ensures that patient care offices/sites have implemented mechanisms that guard against unauthorized or inadvertent disclosure of confidential information to persons inside and outside the managed care organization who should not have access to such information.

RR 7.3 Patients are afforded the opportunity to approve or refuse the release of personal information by the managed care organization, except when such release is required by law.

RR 8.0 The managed care organization assesses and enhances member satisfaction with its services. (Reviewers will consider delegated as well as non-delegated activity). The managed care organization

RR 8.1 Periodically assesses at least a sample of

RR 8.1.1 patient complaints,

RR 8.1.2 requests to change practitioners and/or facilities, and

RR 8.1.3 disenrollments by members.

RR 8.2 Conducts periodic surveys of member satisfaction with the managed care organization's services.

RR 8.3 Identifies sources of dissatisfaction.

RR 8.4 Addresses sources of dissatisfaction.

RR 8.5 Informs practitioners and providers of assessment results.

RR 9.0 If the managed care organization delegates member services activities (eg, complaints and grievances, processes, and member surveys), the following safeguards exist.

RR 9.1 There is a written description of the delegated activities, and the delegate's accountability for these activities.

RR 9.2 The managed care organization monitors the effectiveness of the delegate's member services processes.

PREVENTIVE HEALTH SERVICES

PH 1.0 The managed care organization adopts practice guidelines for the use of preventive health services. (Reviewers will consider delegated as well as non-delegated activity).

- **PH 1.1** Practice guidelines are based on reasonable medical evidence.
- **PH 1.2** Guidelines are developed or adopted with the participation of managed care organization providers.
- **PH 1.3** There is a mechanism for updating the guidelines periodically.
  - **PH 1.3.1** The mechanism is specified by the managed care organization.
- **PH 1.4** Guidelines are developed for the full spectrum of populations enrolled in the managed care organization.

PH 2.0 The managed care organization informs its providers about the guidelines.

PH 3.0 The managed care organization takes steps to assure that members are informed of the guidelines.

- **PH 3.1** The managed care organization takes steps to assure that members use recommended preventive services at appropriate intervals.

PH 4.0 The managed care organization assesses its performance in the use of preventive health services through the QI program. At least annually, the managed care organization monitors and evaluates a minimum of two of the following preventive services, and takes action to improve the use of preventive services as appropriate.

- **PH 4.1** Childhood immunizations
  - **PH 4.1.1** DTP (diphtheria and tetanus toxoids with pertussis vaccine),
  - **PH 4.1.2** OPV (oral poliovirus vaccine),
  - **PH 4.1.3** HIB (hemophilus influenza B conjugate vaccine),
  - **PH 4.1.4** MMR (measles, mumps, and rubella vaccine), and
  - **PH 4.1.5** hepatitis B vaccine.
- **PH 4.2** Adult immunizations
  - **PH 4.2.1** influenza vaccine,
  - **PH 4.2.2** pneumococcal vaccine,
  - **PH 4.2.3** hepatitis B vaccine,

PH 4.2.4 diphtheria and tetanus toxoid, and

PH 4.2.5 rubella screening for women of childbearing age.

PH 4.3 Coronary artery disease risk factor screening and/or counseling

PH 4.3.1 smoking,

PH 4.3.2 cholesterol,

PH 4.3.3 exercise, and

PH 4.3.4 hypertension.

PH 4.4 Cancer screening

PH 4.4.1 breast, and

PH 4.4.2 cervix.

PH 4.5 Counseling for prevention of motor vehicle injury

PH 4.6 Lead toxicity screening

PH 4.7 Sexually transmitted disease screening/prevention

PH 4.8 Prenatal care

PH 4.9 Human immunodeficiency virus (HIV) screening/prevention

PH 4.10 Prevention of unintended pregnancy

PH 4.11 Alcohol and other drug abuse screening/prevention

MEDICAL RECORDS

MR 1.0 Medical records are maintained in a manner that is current, detailed, organized, and permits effective patient care and quality review.

MR 1.1 Records reflect all aspects of patient care, including ancillary services.

MR 1.2 Records are available to health care practitioners at each encounter and to NCQA reviewers.

MR 2.0 The managed care organization sets standards for medical records, systematically reviews the records for conformance, and institutes corrective action when standards are not met.

MR 3.0 Documentation of items on the NCQA Medical Record Review Summary Sheet (see sample, Appendix B) demonstrates that medical records are in conformity with good professional medical practice and appropriate health management.